IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FERRING PHARMACEUTICALS INC., REBIOTIX INC. Plaintiffs, v. FINCH THERAPEUTICS GROUP, INC., FINCH THERAPEUTICS, INC., and FINCH THERAPEUTICS HOLDINGS, LLC. Defendants.	C.A. No. 21-1694-RGA **JURY TRIAL DEMANDED**
FINCH THERAPEUTICS GROUP, INC., FINCH THERAPEUTICS, INC., FINCH THERAPEUTICS HOLDINGS, LLC and REGENTS OF THE UNIVERSITY OF MINNESOTA. Counterclaim-Plaintiffs, v. FERRING PHARMACEUTICALS INC., REBIOTIX INC. Counterclaim-Defendants.	

DEFENDANTS FINCH THERAPEUTICS GROUP, INC., FINCH THERAPEUTICS, INC., AND FINCH THERAPEUTICS HOLDINGS, LLC'S FIRST AMENDED COUNTERCLAIMS AND ANSWER TO COMPLAINT AND AFFIRMATIVE DEFENSES

Defendants/Counterclaim Plaintiffs Finch Therapeutics Group, Inc., Finch Therapeutics, Inc., and Finch Therapeutics Holdings, LLC (collectively, "Finch" or "Defendants") and Counterclaim Plaintiff Regents of the University of Minnesota ("UMN" or "the University") (collectively, "Finch/UMN") through their undersigned attorneys, hereby submit their

Counterclaims to the Complaint filed by Plaintiffs/Counterclaim Defendants Ferring Pharmaceuticals Inc. and Rebiotix Inc. (collectively, "Rebiotix" or "Plaintiffs") and their Answer and Affirmative Defenses.

FINCH'S COUNTERCLAIMS

For its Counterclaims against Plaintiffs, Finch/UMN state as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement and for a declaratory judgment of patent infringement against Rebiotix for infringement of United States Patent Nos. 10,251,914 ("the '914 patent"), 10,286,011 ("the '011 patent"), 10, 286,012 ("the '012 patent"), 10,328,107 ("the '107 patent"), 10,463,702 ("the '702 patent"), and 10,675,309 ("the '309 patent") (collectively, the "Counterclaim Patents"), arising under the patent laws of the United States, 35 U.S.C. § 1 et seq. and under the Declaratory Judgment Act, 28 U.S.C. § 2201 et seq.

2. This action arises out of Rebiotix's submission of a Biologics License Application ("BLA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import RBX2660, which is an enema preparation containing a liquid suspension of fecal microorganisms, in the United States, and Rebiotix's past, current, and/or imminent manufacture, use, sale, offer to sell within the United States, and/or importation into the United States, of RBX2660 prior to the expiration of the Counterclaim Patents.

3. Finch is an industry-leading clinical-stage microbiome therapeutics company. It was co-founded by Mark Smith, Ph.D., a recognized leader in the microbiome field. Dr. Smith holds a Ph.D. in Microbiology from MIT with over 50 peer-reviewed publications in the field. Before founding Finch, Dr. Smith served as President and Research Director of The Microbiome Health Research Institute, Inc. ("OpenBiome"), a nonprofit organization that he co-founded for the purpose of expanding safe access to microbiota transplantation and catalyzing research in the

field. Finch is developing microbiota therapeutics as potential treatments for gastrointestinal diseases and conditions that extend beyond the gut, including candidates for recurrent *C. difficile*, inflammatory bowel disease, autism spectrum disorder, and chronic hepatitis B. Finch has both developed its own technology and acquired rights to technology from key innovators in the microbiome field, including Dr. Thomas Borody, the inventor of the patents named in Rebiotix's Complaint, and researchers at the University of Minnesota, as well as OpenBiome and Arizona State University. Finch employs numerous research scientists and has invested millions of dollars in the research and development of novel microbiota treatments. As a result of its efforts and many innovations, Finch holds an industry leading patent portfolio, with over two hundred issued patents and patent applications, including the seven patents named in the Complaint.

4. Finch (initially through its predecessors) and the University have had a long, ongoing and prolific collaboration in the area of microbiota therapeutics, with Finch and the University collaborating on early clinical trials of Finch's leading candidate, CP101.

5. Some of the key aspects of the Finch and UMN technology, which are embodied in the Counterclaim Patents, relate to the operation of a centralized donor stool bank, the use of standardized and well regulated donors, the manufacture of safe, standardized, stable, ready-to-use products derived from healthy donors, and the use of such products, which are designed to meet certain specifications, to effectuate specific changes in the microbiota of patients suffering from recurring *C. difficile* infection and other diseases and conditions. Finch and OpenBiome, by way of a license from Finch, have practiced certain aspects of this technology to produce more than 60,000 treatments for individuals suffering from a deadly infectious disease known as recurrent *C. difficile* infection, and have received significant industry praise, recognition from the clinical community, and gratitude from their patients for their efforts.

6. Rebiotix, on the other hand, was founded by individuals who had no formal training or experience in the microbiome field. Rebiotix's CEO has acknowledged that she founded Rebiotix after working in the University of Minnesota Venture Center (UMN's technology transfer office), where she learned about microbiota research taking place at UMN, including patent application(s) filed by the UMN inventors covering the same, and where research into technology that was exclusively licensed to Finch was being conducted. Ex. A (https://www.upsizemag.com/category/cover-story/page/5?et_blog) at 5. Over the years, Rebiotix has made substantial use of Finch and UMN technologies, enabling it to advance RBX2660 through clinical development. As Rebiotix admits in its Complaint, it has been carefully monitoring at least Finch, the development of Finch's patented microbiome product candidates, and Finch's extensive patent portfolio, which includes patents exclusively licensed from UMN, as described, for example, in the S-1 filing that Rebiotix quotes extensively in its Complaint. Despite being fully aware of the disclosure of the Counterclaim Patents and the Finch and UMN patent rights for many years, Rebiotix has not made any changes to its products (or their method of manufacture) in view of those patents, nor did it contact Finch or the University prior to filing this lawsuit to discuss a license to, or explain in any way why it believes it does not infringe the Counterclaim Patents and the other Finch patents referenced in the Complaint. As alleged herein, Rebiotix's contentions concerning its non-infringement and the invalidity of the Counterclaim Patents are baseless, and confirm Rebiotix's knowing and willful infringement of the Counterclaim Patents and copying of Finch and UMN technologies.

PARTIES

7. Finch Therapeutics Group, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 200 Inner Belt Road, Suite 400, Somerville, Massachusetts 02143.

8. Finch Therapeutics, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 200 Inner Belt Road, Suite 400, Somerville, Massachusetts 02143. Finch Therapeutics, Inc. is a wholly-owned subsidiary of Finch Therapeutics Group, Inc.

9. Finch Therapeutics Holdings LLC is a Delaware limited liability company having a principal place of business at 200 Inner Belt Road, Suite 400, Somerville, MA 02143. Finch Therapeutics Holdings LLC is a wholly-owned subsidiary of Finch Therapeutics Group, Inc.

10. The University is a public institution of higher education created by charter and perpetuated by the Constitution of the State of Minnesota, Article XIII, Section 3. The University has its principal place of business in Minneapolis, Minnesota.

11. Based on the facts alleged in the Complaint, Ferring Pharmaceuticals Inc. is a private Delaware corporation having its principal place of business at 100 Interpace Parkway, Parsippany, New Jersey 07054.

12. Based on the facts alleged in the Complaint, Rebiotix Inc. is a private Delaware corporation having its principal place of business at 2660 Patton Road, Roseville, Minnesota 55113.

JURISDICTION AND VENUE

13. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 et seq., generally, and 35 U.S.C. § 271, specifically, and this Court has jurisdiction over the subject matter of this action pursuant to the provisions of 28 U.S.C. §§ 1331, 1338(a), and the Declaratory Judgment Act §§ 2201, 2202.

14. Venue is proper in this Court because, among other things, each Counterclaim Defendant is incorporated in the State of Delaware and therefore "resides" in this judicial district.

28 U.S.C. § 1391(c); 28 U.S.C. § 1400(b). Moreover, Ferring Pharmaceuticals, Inc. has litigated previous patent infringement disputes in the District of Delaware.

15. This Court has personal jurisdiction over Ferring Pharmaceuticals Inc. at least because (1) Ferring Pharmaceuticals Inc. has availed itself of the rights and privileges, and has subjected itself to the jurisdiction of this forum by suing Finch in this District, (2) Ferring Pharmaceuticals Inc. is incorporated under the laws of the State of Delaware, (3) Ferring Pharmaceuticals Inc. develops, manufactures, and markets its products throughout the United States, including in this District, and (4) Ferring Pharmaceuticals Inc. maintains a registered agent for service of process in Delaware. Ferring Pharmaceuticals Inc. has not contested jurisdiction in Delaware in one or more prior cases.

16. This Court has personal jurisdiction over Rebiotix Inc. at least because (1) Rebiotix Inc. has availed itself of the rights and privileges, and has subjected itself to the jurisdiction of this forum by suing Finch in this District, (2) Rebiotix Inc. is incorporated under the laws of the State of Delaware, and (3) Rebiotix Inc. maintains a registered agent for service of process in Delaware.

FACTUAL BACKGROUND

The Microbiota and Clostridioides Difficile Infection

17. The human body hosts trillions of microorganisms that together comprise the human microbiota. Collectively, all of these microbiota and their genetic constituents, their genomes, contribute to the microbiome of a specific human anatomical location. These various microbial communities living in and on the body play an essential role in human health, and these microbiota is now among the most heavily researched areas in clinical biology.

18. The human gut microbiota works to enhance the integrity of the gut barrier function, stimulate mucosal immunity, calibrate the systemic immune system, regulate energy metabolism, contribute to the synthesis of essential vitamins and amino acids, and break down

toxic compounds entering the gut, among other functions. Though a healthy gut contains both beneficial and potentially pathogenic bacteria, these organisms can typically coexist within the body without adverse impact on the individual. However, the disruption of this balance by the destruction or loss of key microbes can lead to a reduction in microbial diversity and an increase in bacteria that may become pathogenic when certain criteria are met. This state is known as dysbiosis. Dysbiosis can be caused by certain illnesses, diets, or prolonged use of antibiotics, among other factors. Dysbiosis is believed to increase susceptibility to infections, immune disorders, neurological conditions, cancer, and other potentially life-threatening diseases.

19. One of the pathogenic bacteria involved in human disease is *Clostridioides difficile* (previously known as *Clostridium difficile*), or *C. difficile,* a toxin-producing, spore-forming bacterium. As a spore-former, *C. difficile* exists in two forms: dormant spores and vegetative, toxin-producing bacteria. *C. difficile* infection ("CDI") usually occurs when patients have taken a course of antibiotics that altered their microbiome, thereby finding themselves in a state of dysbiosis. Whereas an individual with a healthy gut microbiome may not be affected by contact with *C. difficile* bacteria, the use of antibiotics can make a patient vulnerable to *C. difficile* infection by suppression of the microbiota and disruption of its community structure, allowing for *C. difficile* to multiply. Once it takes root, *C. difficile* expresses toxins that lead to inflammation of the colon, severe diarrhea, and abdominal pain. In addition to diarrhea and pain, CDI can lead to more serious clinical outcomes including toxic megacolon, perforation of the colon, and death.

20. There are over 450,000 cases of primary CDI and approximately 200,000 cases of recurrent CDI annually in the United States, resulting in more than 44,000 CDI-attributable deaths per year. D.I. 1, Ex. 1 at 109-110. CDI also has a substantial economic impact, with 2.4 million in-patient days and more than $5 billion in direct treatment costs attributed to CDI each year in the

United States alone. D.I. 1, Ex. 1 at 110. The Centers for Disease Control and Prevention considers CDI to be one of the top five most urgent antibiotic resistant threats and the most common cause of healthcare associated infection in the United States.

21. Though antibiotics are believed to cause, or at least contribute to, the onset of CDI, they nonetheless remain, somewhat paradoxically, the current standard of care for treating CDI. CDI must be cleared completely to prevent recurrence of symptoms, particularly when the gut microbiome has been disrupted. The leading CDI antibiotic is vancomycin. Vancomycin is a broad-spectrum treatment, the use of which may cause further disruption and suppression of the microbiota, making it a less than ideal option for the treatment of CDI. Furthermore, vancomycin has no activity against *C. difficile* spores. As a result, when the antibiotic course is completed but the gut microbiome remains disrupted, any residual *C. difficile* spores may germinate into toxin-producing *C. difficile*, resulting in recurrence of CDI (rCDI). To address these problems, fidaxomicin was designed as an alternative, narrow-spectrum antibiotic, with reduced activity against other microbes and some sporicidal activity. Fidaxomicin was approved for the treatment of *C. difficile*-associated diarrhea in 2011. Ex. B (2011 Dificid Label) at 1. However, even though fidaxomicin is more selective in its antimicrobial coverage, it still targets critical members of the gut microbiota that contribute to protection against CDI. Further, although fidaxomicin has some sporicidal activity, it cannot possibly eliminate spores from the patient's environment. Thus, clinical trials show that it is only marginally superior to vancomycin with respect to CDI recurrence rate. Such recurrence is the key driver of morbidity, mortality and cost in CDI care. Without restoration of the microbiome, a patient is likely to continue in this cycle of recurrent CDI. The recurrence risk has been estimated to be about 20%, but increases to about 45% in patients with one recurrence, and to 75% in patients with multiple recurrences.

22. Fecal microbiota transplantation ("FMT") is another option for patients suffering from CDI, though unfortunately not an option that has historically been accessible to many. FMT, also referred to as bacteriotherapy, intestinal microbiota transplantation ("IMT"), or microbiota transplantation therapy ("MTT"), is the process of transplanting bacteria obtained from stool of healthy donors into patients suffering from diseases of dysbiosis, thereby providing the patient with a diverse microbial community from a healthy donor. FMT is a procedure, not a product, and is not approved by the U.S. Food and Drug Administration ("FDA") nor are there FDA-defined standards for testing, processing, and/or delivery of FMT. D.I. 1, Ex. 1 at 2.

23. Though FMT has shown great promise in smaller-scale studies, for decades it remained difficult for physicians to offer FMT due to the challenges of identifying and screening donors as well as processing the collected material in a manner that preserves the fecal microorganisms for storage and later administration to a patient. Thus, there has been a need for reproducible, highly-effective, safe, and standardized treatments for CDI, as well as other diseases linked to disruptions of the gut microbiota.

Finch Therapeutics, Inc.

24. Finch Therapeutics, Inc. was founded in November 2014 by a team of data scientists, clinicians, and microbiologists, seeking to make treatment options for CDI and other diseases safer and more accessible to patients. The founders of Finch Therapeutics, Inc. were motivated to enter the microbiome field when a close friend suffered through multiple *C. difficile* infection (CDI) recurrences over the course of an 18-month period following a routine surgery. Fueled by the frustration of seeing their friend suffer through 18 months of debilitating illness and multiple rounds of failed treatment, the founders sought to develop better options for patients suffering from CDI.

25. Prior to founding Finch, the co-founders of Finch Therapeutics, Inc., including Dr. Mark Smith, the current CEO, and Dr. Zain Kassam, the former CMO, founded OpenBiome, a non-profit stool bank dedicated to expanding safe access to fecal microbiota transplantation.

26. Finch and OpenBiome have maintained a close partnership and have entered into several agreements, including the license of various technology and intellectual property rights. For example, in 2016, Finch and OpenBiome entered into a Master Strategic Affiliation Agreement, pursuant to which Finch manufactured, for several years, FMT products for distribution by OpenBiome for administration to patients suffering from recurrent CDI and not responding to standard therapies. The Finch-manufactured products included a product named "FMP250", which was intended for administration by colonoscopy, sigmoidoscopy, or enema. In less than a decade of operation, OpenBiome has delivered treatments to more than 60,000 patients across a network of more than 1,000 clinics. OpenBiome has a royalty-bearing license to practice certain Finch technology for purposes of manufacturing, selling and distributing its products.

27. Though there are no FDA-approved FMT-based treatments at this time, the FDA has stated that it would allow physicians, in some circumstances, to provide FMT to patients with *C. difficile* not responsive to standard therapy without filing an IND application. Ex. C (FDA Guidance) at 1. OpenBiome has been operating under this policy of enforcement discretion to distribute fecal microbiota transplant products for clinical research and treatment of certain patients with CDI who have not responded to standard therapies. *See* Ex. D (https://www.openbiome.org/regulatory) at 1. Certain entities, including Rebiotix, have asked the FDA to adopt narrower guidance. Ex. E (https://www.regulations.gov/document/FDA-2020-P-1633-0001) at 1, 3. However, numerous stakeholders, including patients, patient advocacy groups, clinicians, and OpenBiome have opposed such changes, as they could severely limit access to FMT

for patients with few other treatment options. Ex. F (https://www.regulations.gov/document/FDA-2013-D-0811-0082) at 1.

28. While it has manufactured products for administration by colonoscopy, sigmoidoscopy, or enema, Finch has chosen, at this time, for its own programs, to focus on microbiome therapeutics that are in capsule form and can be orally administered.

Finch Therapeutics Holdings, LLC

29. Finch Therapeutics Holdings, LLC, formerly Crestovo Holdings LLC ("Crestovo Holdings"), is the parent of Finch Research and Development, LLC (formerly Crestovo LLC ("Crestovo")). In 2015, Crestovo acquired rights to intellectual property owned or controlled by CIPAC Limited, a company that was co-founded by Dr. Thomas Borody, a pioneer in microbiota transplantation. Dr. Borody hypothesized that "patients could benefit by having the 'infected' bowel flora removed . . . and replaced with bowel bacteria from a healthy donor, thus 'crowding out' any remaining pathogens." Ex. G (Borody 1989) at 604. Dr. Borody's work was a success, and in 1989, Dr. Borody and his team published their findings from the treatment of 55 patients. Their report concluded that "[b]y means of bowel-flora-alteration therapy, the resolution of symptoms in those patients who appear to be 'cured' has been so dramatic that we are convinced that an infective aetiology should be pursued vigorously." *Id.*

30. Dr. Borody continued his breakthrough work, expanding his research in the late 1990s to begin evaluating the use of microbiota transplantation in children with autism. His work in this area helped spur further research exploring the role of the microbiome in autism spectrum disorder ("ASD"), including Finch's product candidate for ASD, FIN-211.

31. Following years of research and clinical work, in 2010, Dr. Borody filed his first application for patents directed to stable, conveniently administered microbiome therapeutics

derived from the stool of healthy human donors. Ex. H (AU2010903474). This application would form the basis for the patent family that is now at issue in this litigation. The PCT application for this patent family was published on February 9, 2012, disclosing Dr. Borody's inventions to the public, including Rebiotix.

32. In October 2011, Dr. Borody, through his company CIPAC Limited, entered into a research agreement with UMN, agreeing to sponsor the further development of frozen and freeze-dried microbiota preparations. In March 2012, Dr. Borody, through CIPAC Limited, also entered into a license agreement with UMN, pursuant to which, CIPAC obtained a worldwide, royalty-bearing, exclusive license to certain patents and inventions of the University of Minnesota directed to its microbiota products and processes. In 2015, CIPAC transferred its interest in the license agreement to Crestovo, which is now part of Finch.

Finch Therapeutics Group, Inc.

33. In October 2017, Finch Therapeutics, Inc., announced its merger with Crestovo, forming Finch Therapeutics Group, Inc. Ex. I (https://ir.finchtherapeutics.com/news-releases/news-release-details/finch-therapeutics-and-crestovo-announce-merger-form-finch) at 1.

34. Finch Therapeutics Group, Inc. is a clinical-stage microbiome therapeutics company working to provide therapies to patients suffering from microbiome-mediated diseases. Specifically, Finch Therapeutics Group, Inc. is developing a novel class of drugs designed to deliver missing microbes and restore their clinically relevant biochemical functions to correct dysbiosis and related diseases, including CDI.

35. Through the creation of Finch Therapeutics Group, Inc., Finch Therapeutics, Inc. and Crestovo Holdings, now Finch Therapeutics Holdings, LLC, were able to combine the extensive IP portfolio of Crestovo and Crestovo Holdings and late-stage CDI candidate, CP101,

with Finch Therapeutics, Inc.'s commercial-scale manufacturing capabilities, discovery platform, and significant product pipeline to create a fully integrated microbiome company. Together, Finch Therapeutics Group, Inc., Finch Therapeutics, Inc., and Finch Therapeutics Holdings, LLC are working to develop a consistent product manufactured using a quality-controlled process, to provide patients and physicians with a treatment option in an easily administrable format that is safe and ready for use.

Regents of the University of Minnesota

36. The University is Minnesota's flagship research university and has a long history of innovation, outreach, and public service. The University has over 40,000 undergraduate students, nearly 17,000 graduate and professional students, and about 4,700 faculty.

37. The University supports and facilitates a wide range of research that directly benefits the public both in and beyond the State of Minnesota and consistently ranks among the top U.S. public universities in its amount of research funding. In 2021 alone, the University received over $1.15 billion in research awards from both public and private sources, demonstrating the funders' recognition of the value and promise of the University's research programs.

38. The largest source of research awards for the University remain federal awards, with the National Institutes of Health and the National Science Foundation awarding the most support, including funds of $256 million for COVID-19-related projects. Private research funding for the University's work can originate from business and industry, such as research funding provided by Finch. In 2021, the University was also issued 181 patents from US and foreign patent offices, signaling further recognition of the breakthrough work conducted by the institution and its partners.

39. The University's diverse research initiatives include its Microbiota Therapeutics Program, which is led by Dr. Alexander Khoruts and aims to develop effective and practical

restorative microbiota therapies. The Microbiota Therapeutics Program is one of the pioneering initiatives using FMT (also referred to as Intestinal Microbiota Transplantation or "IMT") to restore intestinal health.

40. Dr. Khoruts, together with Dr. Michael Sadowsky and others in the Microbiota Therapeutics Program, have been working with Finch and its predecessors for nearly a decade to develop novel technologies for the use of FMT not only in patients suffering from CDI, but also a myriad of other conditions, including autism spectrum disorder ("ASD"). In March 2012, the University and Finch entered into an exclusive, royalty-bearing license, which granted Finch and its predecessors the right to make, use, and sell (among other rights) any product covered by the licensed UMN patents. The innovators have filed for patent protection of the inventions arising from this collaboration and are developing clinical product candidates for these indications. The stool donor program at the University has also helped supply material for the manufacture of Finch's product candidates.

Finch Product Candidates

41. Finch and UMN's research efforts, including their pioneering work in the field of FMT and Finch's "Human-First Discovery" platform, have led to the development of the following product candidates for use in patients with diseases of dysbiosis:

CP101

42. CP101 is an orally administered product candidate being developed for the treatment of patients with recurrent CDI. Researchers at the University collaborated with Finch in the development of CP101 and accumulated the initial clinical trial experience and pharmacokinetic data in treating patients with rCDI using this agent.

43. In February 2019, Finch announced that the FDA granted Breakthrough Therapy Designation to Finch's investigational drug CP101 for the treatment of patients with recurrent CDI.

Ex. J (https://ir.finchtherapeutics.com/news-releases/news-release-details/finch-therapeutics-investigational-drug-cp101-granted) at 1. Breakthrough Therapy Designation is intended to expedite the development and review of investigational therapeutics for serious or life-threatening conditions where preliminary clinical evidence indicates that the product may demonstrate a substantial improvement over existing therapies on one or more clinically significant endpoints. *Id.*

44. In June 2020, Finch reported positive topline data from its first of two pivotal trials in treatment of recurrent CDI. Ex. K (https://ir.finchtherapeutics.com/news-releases/news-release-details/finch-therapeutics-announces-positive-topline-results-randomized) at 1. Subsequently, in November 2021, Finch announced positive topline results from a 24-week open-label extension of its Phase 2 placebo-controlled trial evaluating CP101 for the prevention of recurrent CDI. Ex. L (https://ir.finchtherapeutics.com/news-releases/news-release-details/finch-therapeutics-announces-positive-topline-results-prism-ext) at 1. In the same press release, Finch also announced the start of enrollment for its Phase 3 global trial that will evaluate the efficacy and safety of a single oral administration of CP101 for the prevention of recurrent CDI. *Id.* at 1–2.

FIN-211

45. FIN-211 is a product candidate that Finch is developing to address both GI and behavioral symptoms of ASD.

46. Last year, Finch announced that it plans to initiate a Phase 1b study, called "AUSPIRE," of FIN-211 in children with ASD and constipation in the first half of 2022. Ex. M (https://ir.finchtherapeutics.com/news-releases/news-release-details/finch-therapeutics-reports-third-quarter-2021-financial-results) at 2.

FIN-524 and FIN-525

47. Finch has partnered with Takeda to jointly develop two product candidates for the treatments of inflammatory bowel disease ("IBD"): FIN-524 and FIN-525. IBD is an autoimmune condition that causes inflammation of the gastrointestinal tract. Symptoms of IBD include severe, chronic abdominal pain, diarrhea, GI bleeding, weight loss, and fatigue. As current treatment options are ineffective for many people with IBD, there is a large unmet need in these patient populations.

Rebiotix and RBX2660

48. Rebiotix Inc. was founded in 2011 by its current President and CEO, Lee Jones. Immediately prior to founding Rebiotix, Ms. Jones was employed at the Venture Center at the University of Minnesota ("UMN") until June 2011. During her time at the Venture Center, Ms. Jones learned of fecal transplant research being conducted by Drs. Alex Khoruts and Michael Sadowsky at UMN, who are long-time collaborators of Finch and two of the named inventors on patents exclusively licensed to Finch by UMN. Ms. Jones took an interest in their technology, and engaged directly with the UMN researchers for months to better understand the technology and the potential business opportunity. When Drs. Khoruts and Sadowsky found a different partner experienced in the microbiome field to support their research and product development efforts, Ms. Jones left UMN to found Rebiotix, claiming not to need Dr. Khoruts and Dr. Sadowsky's patents and without securing a license to use their patented technology, which was exclusively licensed to Finch instead. Ms. Jones co-founded Rebiotix less than six months after she left her position at UMN with no prior experience or formal training in microbiome therapeutics. Nor did either of Ms. Jones's co-founders have any such formal training: Michael Berman is a medical device investor/entrepreneur and Erwin Kelen is a venture capitalist and angel investor.

49. RBX2660 is an enema product with each dose "consist[ing] of 50 g of human stool/150 mL 0.9% saline/polyethylene glycol 3350 vehicle" "in a single-dose ready-to-use enema bag." Ex. N (Ornstein 2016) at 597; *see also* Ex. O (Blount 2019), Supplementary Information at 2 ("RBX2660 is manufactured as single-dose, ready-to-use units, each in an enema bag containing a 150 mL suspension of $\geq 10^7$ live organisms/mL."). Each dose of RBX2660 "contain[s] $\geq 10^7$ live organisms/mL of suspension." *Id.* According to Rebiotix, RBX2660 contains at least the following classes of bacteria: Actinobacteria, Bacilli, Bacteroidia, Betaproteobacteria, Clostridia, Erysipelotrichia, Gammaproteobacteria, and Verrucomicrobia. Ex. O at 5, 7. Based on the facts alleged in the Complaint, RBX2660 also contains particles of non-living material in the form of insoluble particulate matter and/or rough particulate matter.

50. Based on the facts alleged in the Complaint, to manufacture RBX2660, fecal samples are collected from pre-screened, healthy donors then blended with a solution consisting of saline and polyethylene glycol to form a slurry, which is then filtered to remove insoluble particulate matter. The filtrate produced has a particle size no greater than 0.5 mm. Ex. P (U.S. Publication No. 2017/0327862) at [0041]–[0043]. The donors used to prepare RBX2660 complete "a comprehensive initial health and lifestyle questionnaire and then provide[] blood and stool samples." Ex. N at 597. The "[s]tool samples [a]re tested for *C. difficile* toxin, norovirus, rotavirus, adenovirus, ova and parasites, vancomycin-resistant enterococci, methicillin-resistant Staphylococcus aureus, Vibrios, Listeria, and enteric pathogens." *Id.* The stool is not frozen prior to processing. Ex. Q (U.S. 9,782,445) at 14:34–53.

51. Based on the facts alleged in the Complaint, RBX2660 is packaged in a 250 mL ethylene vinyl acetate bag, and if approved by the FDA, would be indicated "to reduce the recurrence of *Clostridium difficile* infection (CDI) in adults following antibiotic treatment for

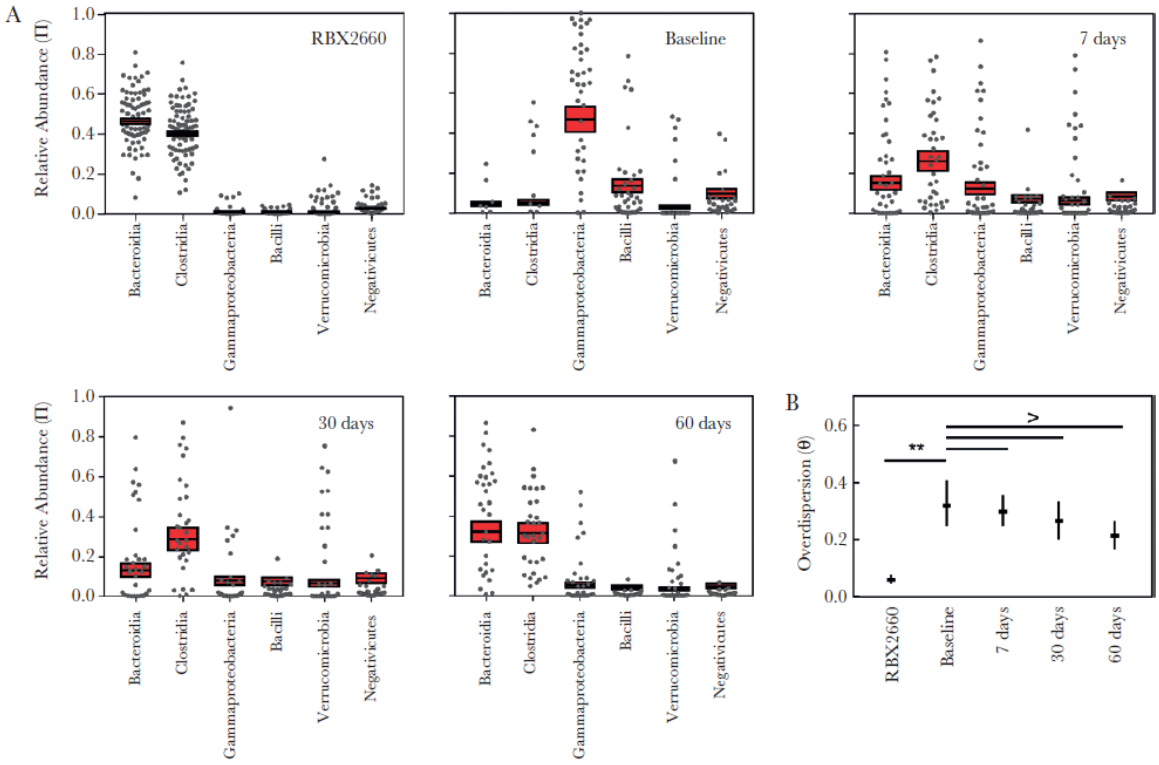
recurrent *Clostridium difficile* infection." The RBX2660 enema delivery system comes with at least flexible tubing:

Ex. R (SGNA Presentation) at 9.

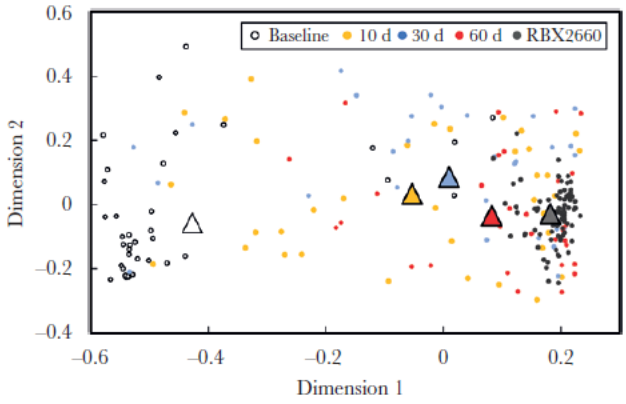
52. RBX2660 is "stored frozen at ≤ −80°C in a secure location at the manufacturer and then thawed prior to shipment to the clinical site." Ex. N at 597; *see also* Ex. O, Supplementary Information at 2 ("As needed, RBX2660 doses were shipped frozen to the site in a temperature-controlled container, thawed in a refrigerator for 24 hours, and administered within 48 hours after thawing.").

53. Rebiotix has reported overall efficacy rates of at least 87% for enema delivery of RBX2660 to patients with recurrent CDI. *Id.* at 599. Rebiotix has further reported that "[a]fter treatment, Bacteroidia, Clostridia, and alpha diversity increased among RBX2660 responders, concomitant with a decrease of Gammaproteobacteria and Bacilli." Ex. O at 1. Rebiotix has

reported the following results for the "taxonomic compositions among RBX2660 product samples and responder samples before treatment and . . . after treatment":



Ex. O at 5. Rebiotix has also reported that "[a]fter treatment, RBX2660 responders' microbiomes were more similar to RBX2660. . . . At 10, 30, and 60 days after treatment, ϕ decreased to 0.424, 0.294, and 0.261, respectively, confirming progression of participants' microbiomes to more closely resemble RBX2660," providing the following data:



Id. at 4.

PATENTS-IN-SUIT

54. The Counterclaim Patents are directed to specific, concrete improvements in microbiome therapeutics generally, and the practice of FMT in particular. Before Finch/UMN's inventions, patients and physicians bore the burden of locating a suitable donor, screening, and collecting the sample prior to transplantation, without specific guidelines of what criteria the material collected needed to meet or the specific changes that should be seen in a patient's microbiome following transplantation. This system created great barriers to access to FMT, took physicians' time away from the practice of medicine, and reduced confidence in a procedure that lacked the standardization typically seen in then-existing medicine. By contrast, the Counterclaim Patents solve these specific problems of creating a safe, ready-to-use, and scalable stool donor-derived stool product that meets certain limitations and effectuates specific results in a patient, can be manufactured in a central location, preserves viable bacteria within the stool, and is stable during storage and transportation.

55. The Counterclaim Patents are specifically directed to the collection of donor samples at a central facility and the processing and preparation of pharmaceutical compositions for shipment to remote locations, including a hospital or pharmacy, for administration. For example, the '107 patent claims "receiving at a central location" samples from a donor. Likewise, the '702 patent claims "[a]n enema product configured for transporting to a remote facility" and "shipping the enema product to a remote facility." The '309 patent claims "[a]n enema delivery system configured for transporting to a remote facility." This is a distinct improvement upon prior work, where fecal transplants were performed within hours, if not minutes, after sample collection from donors who were typically family members or close friends of the patient, or even medical personnel working in the hospital where the transplants were taking place. These inventions

provide a previously unmet benefit for the patient of avoiding the difficult and often awkward task of finding a donor.

56. The Counterclaim Patents further claim specific steps used to ensure the safety and efficacy of the therapy, including the addition of specific excipients. For example, the '107 patent claims "testing the stool sample for pathogens," "mixing the stool sample with a cryoprotectant to form a mixture," and "homogenizing the mixture." Likewise, the '702 patent claims "a pharmaceutical composition [that] comprises saline, a cryoprotectant, and the substantially entire microbiota of a stool sample."

57. The Counterclaim Patents further claim a specific container and/or delivery system that allows for the transport and delivery of an effective treatment to patients without requiring the administering physician to directly handle the fecal material. For example, the '702 patent claims "[a]n enema delivery system comprising a bag, flexible tubing, and a pharmaceutical composition within the bag, wherein the pharmaceutical composition is formulated for enema delivery directly from the bag via the flexible tubing" and specifies that the bag "comprises an oxygen-resistant material."

58. The '914, '011, '702 and '309 patents further claim a specific use for the claimed composition. For example, the '914 patent claims "[a] method of [effectuating certain changes] in a patient in need thereof and having a *Clostridium difficile* infection" and the '011 patent further claims a "patient [having] a recurrent *Clostridium difficile* infection" and "patient [ ] at risk of developing a recurrent *Clostridium difficile* infection." Similarly, the '309 patent claims a "pharmaceutical composition [ ] in an amount effective for treating recurrence of *C. difficile* infection" and the '702 patent claims "substantially entire microbiota [ ] in an amount effective for treating a *C. difficile* infection."

59. The Counterclaim Patents further claim certain criteria that must be met by the composition being used to treat patients. For example, each of the ’914, ’011, and ’012 patents requires a “human fecal donor’s intestinal microbiota comprising at least 6 different classes of bacteria” selected from an enumerated list and that the “microbe preparation comprises no particle having a size of greater than 0.5 mm.”

60. The Counterclaim Patents further claim specific changes to the patient’s microbiota to be facilitated by the administration of the compositions. For example, the ’914 patent claims a “method of decreasing the relative abundance of one or more members of the phylum Proteobacteria . . . wherein the relative abundance of one or more members of the phylum Proteobacteria is reduced by at least 10% following administration.” Likewise, the ’011 patent claims a “method of increasing fecal microbiota diversity in a human patient . . . wherein the administering increases the diversity of said patient's fecal microbiota compared to before said administering.” Likewise, the ’012 patent claims a “method of increasing the relative abundance of one or more members of the phylum Firmicutes . . . wherein the administering increases the relative abundance of total members of the phylum Firmicutes by at least 20% compared to before said administering.”

61. Thus, the inventions of Finch and the University enable patients to receive a life-changing treatment in their hometown from a donor located across the country, with the knowledge and assurance that the materials administered are of a standard formulation having demonstrated safety and efficacy and in a ready-to-use form that minimizes the burden on the administering physician.

62. Developing a product with particular characteristics through a method of manufacturing that uses specific additives, processing steps, and delivery system, as well as the

methods of using said product to generate specific changes to a patient's microbiome, is neither abstract, nor in any way preempts the field of microbiota therapeutics. Instead, the Counterclaim Patents cover specific and concrete processes and materials that enable the production of safe, effective, and reproducible microbiota therapeutics that can be made available to patients in even the most remote locales.

63. On April 9, 2019, the USPTO duly and legally issued United States Patent No. 10,251,914 entitled "Compositions and Methods for Transplantation of Colon Microbiota" to inventors Michael J. Sadowsky, Alexander Khoruts, Alexa R. Weingarden, and Matthew J. Hamilton. A copy of the '914 patent is attached as Exhibit S. The '914 patent is assigned to Regents of the University of Minnesota.

64. The '914 patent is valid and enforceable.

65. On May 14, 2019, the USPTO duly and legally issued United States Patent No. 10,286,011 entitled "Compositions and Methods for Transplantation of Colon Microbiota" to inventors Michael J. Sadowsky, Alexander Khoruts, Alexa R. Weingarden, and Matthew J. Hamilton. A copy of the '011 patent is attached as Exhibit T. The '011 patent is assigned to Regents of the University of Minnesota.

66. The '011 patent is valid and enforceable.

67. On May 14, 2019, the USPTO duly and legally issued United States Patent No. 10,286,012 entitled "Compositions and Methods for Transplantation of Colon Microbiota" to inventors Michael J. Sadowsky, Alexander Khoruts, Alexa R. Weingarden, and Matthew J. Hamilton. A copy of the '012 patent is attached as Exhibit U. The '012 patent is assigned to Regents of the University of Minnesota.

68. The '012 patent is valid and enforceable.

69. On June 25, 2019, the USPTO duly and legally issued United States Patent No. 10,328,107 entitled "Compositions for Fecal Floral Transplantation and Methods for Making and Using Them and Devices for Delivering Them" to inventor Thomas Julius Borody. A copy of the '107 patent is attached to the Complaint as Exhibit 4. The '107 patent is assigned to Finch Therapeutics Holdings LLC.

70. The '107 patent is valid and enforceable.

71. In granting the '107 patent, the Examiner acknowledged other work in the field, including that of Dr. Hlavka, but found that "Hlavka is different from the claimed invention in that the fecal sample is taught to be preserved via freezing after collection from the donor, which teaches away from the requirement that the stool sample is 'non-frozen.' . . . There would be no reason for a person with ordinary skill in the art at the time of invention to modify Hlavka's preparation method by requiring that the donor fecal sample be non-frozen." Ex. V (April 22, 2019 Notice of Allowance) at 2–3.

72. On November 5, 2019, the USPTO duly and legally issued United States Patent No. 10,463,702 entitled "Compositions for Fecal Floral Transplantation and Methods for Making and Using Them and Devices for Delivering Them" to inventor Thomas J. Borody. A copy of the '702 patent is attached to the Complaint as Exhibit 3. The '702 patent is assigned to Finch Therapeutics Holdings LLC.

73. The '702 patent is valid and enforceable.

74. In granting the '702 patent, the Examiner acknowledged other work in the field, but found that the prior art "stool composition differs from the claimed invention in that it does not comprise a cryoprotectant and the storage vessel is not defined as comprising an oxygen-resistant material. . . . [and] there is no reason or motivation [in the prior art] to store [the] stool composition

using [an] oxygen-free barrier packaging." Ex. W (September 23, 2019 Notice of Allowance) at 2–3.

75. On June 9, 2020, the USPTO duly and legally issued United States Patent No. 10,675,309 entitled "Compositions for Fecal Floral Transplantation and Methods for Making and Using Them and Devices for Delivering Them" to inventor Thomas Borody. A copy of the '309 patent is attached to the Complaint as Exhibit 2. The '309 patent is assigned to Finch Therapeutics Holdings LLC.

76. The '309 patent is valid and enforceable.

77. In granting the '309 patent, the Examiner acknowledged prior work in the field, but found that the stool composition "is not taught to be specifically free of rough particulate matter, combined with a cryoprotectant, and placed in [a] sealed container having a flexible tubing. Since the saline mixed with the stool sample is taught to be preservative-free, it would not be obvious to add a cryoprotectant, which is a preservative." Ex. X (March 20, 2020 Notice of Allowance) at 4.

78. Rebiotix had actual or constructive knowledge and notice of infringement as to each of the Counterclaim Patents. The PCT Application for the patent family that includes the '107, '702, and '309 patents ("the Borody family") published February 9, 2012. The PCT Application for the patent family that includes the '014, '011, and '012 patents ("the Sadowsky family") published September 13, 2012. Rebiotix also filed the present Declaratory Judgment action, which includes the '107, '702, and '309 patents. In the Complaint, Rebiotix points to Finch's S-1 filing, which was submitted on February 26, 2021, evidencing Rebiotix's monitoring of Finch, the development of its patented products, and its patent portfolio generally. As quoted by Rebiotix in the Complaint, the S-1 filing states:

> ***We have built multi-layered patent protection with significant longevity***. We have a large and diverse patent portfolio that

> embodies pioneering work in the microbiome field. Our patent portfolio consists of over 50 issued U.S. and foreign patents, as well as over 130 patent applications, that have broad relevance for the industry and provide multi-layered protection for our product candidates . . .

D.I. 1, Ex. 1 at 4. Finch's S-1 filing further identifies the Borody family, specifically identifying the '107 patent. D.I. 1, Ex. 1 at 135. Rebiotix further specifically identifies the filing timeline and issuance dates of the '702 and '309 patents in the Complaint. Finch's S-1 filing also identifies the Sadowsky family, specifically identifying all three of the '011, '012, and '914 patents. *Id.* at 136. As such, Rebiotix knew, should have known, or was willfully blind as to the existence of the Counterclaim Patents at the time of Rebiotix's infringing acts.

79. Rebiotix's infringement of the Counterclaim Patents has been, and continues to be, willful because Rebiotix has committed and continues to commit acts of infringement even though Rebiotix knew or should have known that its actions constituted an unjustifiably high risk of infringement.

COUNT 1: INFRINGEMENT OF U.S. PATENT NO. 10,251,914

80. Finch/UMN reallege paragraphs 1–79 as if fully set forth herein.

81. Claim 1 of the '914 patent recites:

> [a] A method of decreasing the relative abundance of one or more members of the phylum Proteobacteria in a patient in need thereof and having a Clostridium difficile infection, the method comprising:
>
> [b] administering to said patient an effective amount of a pharmaceutical composition comprising;
>
> [c] a human fecal microbe preparation comprising a pharmaceutically acceptable carrier and a human fecal donor's intestinal microbiota comprising;
>
> [d] at least 6 different classes of bacteria selected from the group consisting of Actinobacteria, Bacteroidia, Bacilli, Clostridia, Erysipelotrichi, Alphaproteobacteria, Betaproteobacteria, Gammaproteobacteria, Mollicutes, and Verrucomicrobiae;

> [e] wherein said human fecal microbe preparation comprises particles of non-living material and particles of biological material;
>
> [f] and said human fecal microbe preparation comprises no particle having a size of greater than 0.5 mm;
>
> [g] wherein the relative abundance of one or more members of the phylum Proteobacteria is reduced by at least 10% following administration of said pharmaceutical composition.

82. Rebiotix has reported that administration of RBX2660 to patients with recurrent CDI decreases the relative abundance of at least Gammaproteobacteria, a member of the phylum of Proteobacteria, by at least 10%, *see* ¶¶49–53 of the Counterclaims, as required by elements (a) and (b) of claim 1 of the '914 patent.

83. Each dose of RBX2660 consists of 50 g of human stool and 150 mL 0.9% saline and polyethylene glycol 3350, *see* ¶¶49–53 of the Counterclaims, as required by element (c) of claim 1 of the '914 patent.

84. Each dose of RBX2660 contains bacteria from at least 6 classes of bacteria, including at least Actinobacteria, Bacilli, Bacteroidia, Betaproteobacteria, Clostridia, Erysipelotrichia, Gammaproteobacteria, and Verrucomicrobia, *see* ¶¶49–53 of the Counterclaims, as required by element (d) of claim 1 of the '914 patent.

85. Each dose of RBX2660 contains particles of biological material and non-living material, *see* ¶¶49–53 of the Counterclaims, as required by element (e) of claim 1 of the '914 patent.

86. The method of manufacturing RBX2660 involves the use of filters having a pore size of 0.5 mm of less, resulting in a composition having no particle of a size greater than 0.5 mm, *see* ¶¶49–53 of the Counterclaims, as required by element (f) of claim 1 of the '914 patent.

87. Rebiotix has reported that the relative abundance of at least Gammaproteobacteria, a member of the phylum Proteobacteria, was reduced by at least 10% following administration of

RBX2660, *see* ¶¶49–53 of the Counterclaims, as required by element (g) of claim 1 of the '914 patent.

88. Thus, the use and/or administration of RBX2660 will meet each and every limitation of at least claim 1 of the '914 patent, either literally and/or under the doctrine of equivalents.

89. Based on the facts alleged in the Complaint, Rebiotix previously provided RBX2660 to patients under the FDA's enforcement discretion policy. On information and belief, these activities are, at least in part, for commercial purposes, and hence are not "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." 35 U.S.C. § 271(e)(1). At least these activities are thus not protected by the provisions of 35 U.S. Code § 271(e)(1).

90. Such use of RBX2660 in patients shows that Rebiotix is practicing, and/or is directing or instructing others to practice, the claimed method and thus using Finch/UMN's patented technology. Accordingly, an actual and immediate controversy exists regarding Rebiotix's infringement of the '914 patent under 35 U.S.C. § 271.

91. Rebiotix's use, offer to sell, or sale of RBX2660 in the United States during the term of the '914 patent infringes at least one claim of the '914 patent under 35 U.S.C. § 271.

92. RBX2660, when offered for sale, sold, and/or when used as directed, is used in a manner that directly infringes at least one of the claims of the '914 patent either literally and/or under the doctrine of equivalents.

93. The use of RBX2660 constitutes a material part of at least claim 1 of the '914 patent. Rebiotix knows that RBX2660 is especially made or adapted for use in manner that

infringes at least claim 1 of the ’914 patent, either literally and/or under the doctrine of equivalents and that RBX2660 is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

94. Thus, the offering to sell or sale of RBX2660 contributorily infringes at least claim 1 of the ’914 patent, either literally and/or under the doctrine of equivalents.

95. Rebiotix had knowledge of the ’914 patent and, by the information it provides with RBX2660, knows or should know that it has aided and abetted another’s direct infringement of at least claim 1 of the ’914 patent, either literally and/or under the doctrine of equivalents.

96. The manufacture, offering to sell, or sale of RBX2660 by Rebiotix actively induces infringement of at least claim 1 of the ’914 patent, either literally and/or under the doctrine of equivalents.

97. Rebiotix has performed and continues to perform these affirmative acts with knowledge of the ’914 patent and with the intent, or willful blindness, that the acts directly infringe the ’914 patent. In filing the present Declaratory Judgment action, Rebiotix cited extensively to Finch’s S-1 filing, which not only discusses the Sadowsky family generally, but also specifically calls out the ’914 patent.

98. Rebiotix’s acts of infringement have caused damage to Finch/UMN, and Finch/UMN are entitled to recover from Rebiotix the damages they have sustained as a result of Rebiotix’s wrongful acts in an amount subject to proof at trial.

99. Rebiotix’s acts of infringement have caused, and unless restrained and enjoined, will continue to cause irreparable injury and damage to Finch/UMN for which there is no adequate remedy at law.

100. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Finch/UMN's reasonable attorney fees.

COUNT 2: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 10,251,914

101. Finch/UMN reallege paragraphs 1–100 as if fully set forth herein.

102. Based on the facts alleged in the Complaint, Rebiotix completed rolling submission of its Biologics License Application ("BLA") No. 125739 ("Rebiotix's BLA") seeking regulatory approval to market and sell RBX2660. Based on the facts alleged in the Complaint, Rebiotix requested that the BLA receive accelerated approval and priority review.

103. As shown in Paragraphs 81–88 of the Counterclaims, the use and/or administration of RBX2660 infringes each and every limitation of at least claim 1 of the '914 patent, either literally and/or under the doctrine of equivalents.

104. Rebiotix has declared its intent to manufacture, use, offer to sell, sell in the United States or to import into the United States RBX2660 in the event that the FDA approves Rebiotix's BLA. Because the use and/or administration of RBX2660 practices the claimed method, an actual and immediate controversy exists regarding Rebiotix's infringement of the '914 patent under 35 U.S.C. § 271.

105. RBX2660, when offered for sale, sold, and/or when used as directed, would be used in a manner that would directly infringe at least claim 1 of the '914 patent either literally and/or under the doctrine of equivalents.

106. The use of RBX2660 constitutes a material part of at least claim 1 of the '914 patent. Rebiotix knows that RBX2660 is especially made or adapted for use in manner that infringes at least claim 1 of the '914 patent, either literally and/or under the doctrine of equivalents

and that RBX2660 is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

107. Thus, the offering to sell or sale of RBX2660 would contributorily infringe at least claim 1 of the '914 patent, either literally and/or under the doctrine of equivalents.

108. Rebiotix had knowledge of the '914 patent and, by the information it provides with RBX2660, knows or should know that it will aid and abet another's direct infringement of at least claim 1 of the '914 patent, either literally and/or under the doctrine of equivalents.

109. The manufacture, offering to sell, or sale of RBX2660 by Rebiotix would actively induce infringement of at least claim 1 of the '914 patent, either literally and/or under the doctrine of equivalents.

110. Rebiotix will perform these affirmative acts with knowledge of the '914 patent and with the intent, or willful blindness, that the acts directly infringe the '914 patent. In filing the present Declaratory Judgment action, Rebiotix cited extensively to Finch's S-1 filing, which not only discusses the Sadowsky family generally, but also specifically calls out the '914 patent.

111. Rebiotix's acts of infringement have caused, and unless restrained and enjoined, will continue to cause irreparable injury and damage to Finch/UMN for which there is no adequate remedy at law.

112. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Finch/UMN's reasonable attorney fees.

COUNT 3: INFRINGEMENT OF U.S. PATENT NO. 10,286,011

113. Finch/UMN reallege paragraphs 1–112 as if fully set forth herein.

114. Claim 1 of the '011 patent recites:

> [a] A method of increasing fecal microbiota diversity in a human patient in need thereof and having a *Clostridium difficile* infection (CDI), the method comprising:

> [b] administering to said patient an effective amount of a pharmaceutical composition comprising;
>
> [c] a human fecal microbe preparation comprising;
>
> [d] a pharmaceutically acceptable carrier and a human fecal extract comprising;
>
> [e] a healthy human fecal donor's intestinal microbiota comprising;
>
> [f] at least 6 different classes of bacteria selected from the group consisting of Actinobacteria, Bacteroidia, Bacilli, Clostridia, Erysipelotrichi, Alphaproteobacteria, Betaproteobacteria, Gammaproteobacteria, Mollicutes, and Verrucomicrobiae;
>
> [g] wherein said human fecal extract comprises particles of nonliving material and particles of biological material; and
>
> [h] said human fecal extract comprises no particle having a size of greater than 0.5 mm;
>
> [i] wherein the administering increases the diversity of said patient's fecal microbiota compared to before said administering; and
>
> [j] wherein said patient's fecal microbiota after said administering cluster more closely to the microbiota of the donor's feces using Yue and Clayton's Theta Index.

115. Rebiotix has reported that administration of RBX2660 to patients with recurrent CDI increases fecal microbiota diversity in patients with a CDI, *see* ¶¶49–53 of the Counterclaims, as required by elements (a), (b), and (i) of claim 1 of the '011 patent.

116. Each dose of RBX2660 consists of 50 g of human stool from a healthy human donor and 150 mL 0.9% saline and polyethylene glycol 3350, *see* ¶¶49–53 of the Counterclaims, as required by elements (c), (d) and (e) of claim 1 of the '011 patent.

117. Each dose of RBX2660 contains bacteria from at least 6 classes of bacteria, including at least Actinobacteria, Bacilli, Bacteroidia, Betaproteobacteria, Clostridia, Erysipelotrichia, Gammaproteobacteria, and Verrucomicrobia, *see* ¶¶49–53 of the Counterclaims, as required by element (f) of claim 1 of the '011 patent.

118. Each dose of RBX2660 contains particles of biological material and non-living material, *see* ¶¶49–53 of the Counterclaims, as required by element (g) of claim 1 of the '011 patent.

119. The method of manufacturing RBX2660 involves the use of filters having a pore size of 0.5 mm of less, resulting in a composition having no particle of a size greater than 0.5 mm, *see* ¶¶49–53 of the Counterclaims, as required by element (h) of claim 1 of the '011 patent.

120. Rebiotix has reported that, based on a similarity index, the patient's fecal microbiota clusters more closely to the composition of RBX2660, or the donor's fecal microbiota, following administration of RBX2660, *see* ¶¶49–53 of the Counterclaims, as required by element (j) of claim 1 of the '011 patent.

121. Thus, the use and/or administration of RBX2660 will meet each and every limitation of at least claim 1 of the '011 patent, either literally and/or under the doctrine of equivalents.

122. Based on the facts alleged in the Complaint, Rebiotix previously provided RBX2660 to patients under the FDA's enforcement discretion policy. On information and belief, these activities are, at least in part, for commercial purposes, and hence are not "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." 35 U.S.C. § 271(e)(1). At least these activities are thus not protected by the provisions of 35 U.S. Code § 271(e)(1).

123. Such use of RBX2660 in patients shows that Rebiotix is practicing, and/or is directing or instructing others to practice, the claimed method and thus using Finch/UMN's

patented technology. Accordingly, an actual and immediate controversy exists regarding Rebiotix's infringement of the '011 patent under 35 U.S.C. § 271.

124. Rebiotix's use, offer to sell, or sale of RBX2660 in the United States during the term of the '011 patent infringes at least one claim of the '011 patent under 35 U.S.C. § 271.

125. RBX2660, when offered for sale, sold, and/or when used as directed, is used in a manner that directly infringes at least one of the claims of the '011 patent either literally and/or under the doctrine of equivalents.

126. The use of RBX2660 constitutes a material part of at least claim 1 of the '011 patent. Rebiotix knows that RBX2660 is especially made or adapted for use in manner that infringes at least claim 1 of the '011 patent, either literally and/or under the doctrine of equivalents and that RBX2660 is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

127. Thus, the offering to sell or sale of RBX2660 contributorily infringes at least claim 1 of the '011 patent, either literally and/or under the doctrine of equivalents.

128. Rebiotix had knowledge of the '011 patent and, by the information it provides with RBX2660, knows or should know that it aided and abetted another's direct infringement of at least claim 1 of the '011 patent, either literally and/or under the doctrine of equivalents.

129. The manufacture, offering to sell, or sale of RBX2660 by Rebiotix actively induces infringement of at least claim 1 of the '011 patent, either literally and/or under the doctrine of equivalents.

130. Rebiotix has performed and continues to perform these affirmative acts with knowledge of the '011 patent and with the intent, or willful blindness, that the acts directly infringe the '011 patent. In filing the present Declaratory Judgment action, Rebiotix cited extensively to

Finch's S-1 filing, which not only discusses the Sadowsky family generally, but also specifically calls out the '011 patent.

131. Rebiotix's acts of infringement have caused damage to Finch/UMN, and Finch/UMN are entitled to recover from Rebiotix the damages they have sustained as a result of Rebiotix's wrongful acts in an amount subject to proof at trial.

132. Rebiotix's acts of infringement have caused, and unless restrained and enjoined, will continue to cause irreparable injury and damage to Finch/UMN for which there is no adequate remedy at law.

133. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Finch/UMN's reasonable attorney fees.

COUNT 4: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 10,286,011

134. Finch/UMN reallege paragraphs 1–133 as if fully set forth herein.

135. Based on the facts alleged in the Complaint, Rebiotix completed rolling submission of its BLA seeking regulatory approval to market and sell RBX2660. Based on the facts alleged in the Complaint, Rebiotix requested that the BLA receive accelerated approval and priority review.

136. As shown in Paragraphs 114–121 of the Counterclaims, the use and/or administration of RBX2660 infringes each and every limitation of at least claim 1 of the '011 patent, either literally and/or under the doctrine of equivalents.

137. Rebiotix has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States RBX2660 in the event that the FDA approves Rebiotix's BLA. Because the use and/or administration of RBX2660 practices the claimed method, an actual and immediate controversy exists regarding Rebiotix's infringement of the '011 patent under 35 U.S.C. § 271.

138. RBX2660, when offered for sale, sold, and/or when used as directed, would be used in a manner that would directly infringe at least claim 1 of the ’011 patent either literally and/or under the doctrine of equivalents.

139. The use of RBX2660 constitutes a material part of at least claim 1 of the ’011 patent. Rebiotix knows that RBX2660 is especially made or adapted for use in manner that infringes at least claim 1 of the ’011 patent, either literally and/or under the doctrine of equivalents and that RBX2660 is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

140. Thus, the offering to sell or sale of RBX2660 would contributorily infringe at least claim 1 of the ’011 patent, either literally and/or under the doctrine of equivalents.

141. Rebiotix had knowledge of the ’011 patent and, by the information it provides with RBX2660, knows or should know that it will aid and abet another’s direct infringement of at least claim 1 of the ’011 patent, either literally and/or under the doctrine of equivalents.

142. The manufacture, offering to sell, or sale of RBX2660 by Rebiotix would actively induce infringement of at least claim 1 of the ’011 patent, either literally and/or under the doctrine of equivalents.

143. Rebiotix will perform these affirmative acts with knowledge of the ’011 patent and with the intent, or willful blindness, that the acts directly infringe the ’011 patent. In filing the present Declaratory Judgment action, Rebiotix cited extensively to Finch’s S-1 filing, which not only discusses the Sadowsky family generally, but also specifically calls out the ’011 patent.

144. Rebiotix’s acts of infringement have caused, and unless restrained and enjoined, will continue to cause irreparable injury and damage to Finch/UMN for which there is no adequate remedy at law.

145. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Finch/UMN's reasonable attorney fees.

COUNT 5: INFRINGEMENT OF U.S. PATENT NO. 10,286,012

146. Finch/UMN reallege paragraphs 1–145 as if fully set forth herein.

147. Claim 1 of the '012 patent recites:

> [a] A method of increasing the relative abundance of one or more members of the phylum *Firmicutes* in a patient in need thereof, the method comprising:
>
> [b] administering to said patient an effective amount of a pharmaceutical composition comprising;
>
> [c] a human fecal microbe preparation comprising a pharmaceutically acceptable carrier and a human fecal extract comprising;
>
> [d] a healthy human fecal donor's intestinal microbiota comprising at least 6 different classes of bacteria selected from the group consisting of Actinobacteria, Bacteroidia, Bacilli, Clostridia, Erysipelotrichi, Alphaproteobacteria, Betaproteobacteria, Gammaproteobacteria, Mollicutes, and Verrucomicrobiae;
>
> [e] wherein said human fecal extract comprises particles of nonliving material and particles of biological material; and
>
> [f] said human fecal extract comprises no particle having a size of greater than 0.5 mm; and
>
> [g] wherein the administering increases the relative abundance of total members of the phylum *Firmicutes* by at least 20% compared to before said administering.

148. Rebiotix has reported that administration of RBX2660 to patients with recurrent CDI increases the relative abundance of total members of the phylum *Firmicutes* by at least 20%, *see* ¶¶49–53 of the Counterclaims, as required by elements (a), (b), and (g) of claim 1 of the '012 patent.

149. Each dose of RBX2660 consists of 50 g of human stool from a healthy human donor and 150 mL 0.9% saline and polyethylene glycol 3350, *see* ¶¶49–53 of the Counterclaims, as required by element (c) of claim 1 of the '012 patent.

150. Each dose of RBX2660 contains bacteria from at least 6 classes of bacteria, including at least Actinobacteria, Bacilli, Bacteroidia, Betaproteobacteria, Clostridia, Erysipelotrichia, Gammaproteobacteria, and Verrucomicrobia, *see* ¶¶49–53 of the Counterclaims, as required by element (d) of claim 1 of the '012 patent.

151. Each dose of RBX2660 contains particles of biological material and non-living material, *see* ¶¶49–53 of the Counterclaims, as required by element (e) of claim 1 of the '012 patent.

152. The method of manufacturing RBX2660 involves the use of filters having a pore size of 0.5 mm of less, resulting in a composition having no particle of a size greater than 0.5 mm, *see* ¶¶49–53 of the Counterclaims, as required by element (f) of claim 1 of the '012 patent.

153. Thus, the use and/or administration of RBX2660 will meet each and every limitation of at least claim 1 of the '012 patent, either literally and/or under the doctrine of equivalents.

154. Based on the facts alleged in the Complaint, Rebiotix previously provided RBX2660 to patients under the FDA's enforcement discretion policy. On information and belief, these activities are, at least in part, for commercial purposes, and hence are not "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." 35 U.S.C. § 271(e)(1). At least these activities are thus not protected by the provisions of 35 U.S. Code § 271(e)(1).

155. Such use of RBX2660 in patients shows that Rebiotix is practicing, and/or is directing or instructing others to practice, the claimed method and thus using Finch/UMN's patented technology. Accordingly, an actual and immediate controversy exists regarding Rebiotix's infringement of the '012 patent under 35 U.S.C. § 271.

156. Rebiotix's use, offer to sell, or sale of RBX2660 in the United States during the term of the '012 patent infringes at least claim 1 of the '012 patent under 35 U.S.C. § 271.

157. RBX2660, when offered for sale, sold, and/or when used as directed, is used in a manner that directly infringes at claim 1 of the '012 patent either literally and/or under the doctrine of equivalents.

158. The use of RBX2660 constitutes a material part of at least claim 1 of the '012 patent. Rebiotix knows that RBX2660 is especially made or adapted for use in manner that infringes at least claim 1 of the '012 patent, either literally and/or under the doctrine of equivalents and that RBX2660 is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

159. Thus, the offering to sell or sale of RBX2660 contributorily infringes at least claim 1 of the '012 patent, either literally and/or under the doctrine of equivalents.

160. Rebiotix had knowledge of the '012 patent and, by the information it provides with RBX2660, knows or should know that it aided and abetted another's direct infringement of at least claim 1 of the '012 patent, either literally and/or under the doctrine of equivalents.

161. The manufacture, offering to sell, or sale of RBX2660 by Rebiotix actively induces infringement of at least claim 1 of the '012 patent, either literally and/or under the doctrine of equivalents.

162. Rebiotix has performed and continues to perform these affirmative acts with knowledge of the '012 patent and with the intent, or willful blindness, that the acts directly infringe the '012 patent. In filing the present Declaratory Judgment action, Rebiotix cited extensively to Finch's S-1 filing, which not only discusses the Sadowsky family generally, but also specifically calls out the '012 patent.

163. Rebiotix's acts of infringement have caused damage to Finch/UMN, and Finch/UMN are entitled to recover from Rebiotix the damages they have sustained as a result of Rebiotix's wrongful acts in an amount subject to proof at trial.

164. Rebiotix's acts of infringement have caused, and unless restrained and enjoined, will continue to cause irreparable injury and damage to Finch/UMN for which there is no adequate remedy at law.

165. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Finch/UMN's reasonable attorney fees.

COUNT 6: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 10,286,012

166. Finch/UMN reallege paragraphs 1–165 as if fully set forth herein.

167. Based on the facts alleged in the Complaint, Rebiotix completed rolling submission of its BLA seeking regulatory approval to market and sell RBX2660. Based on the facts alleged in the Complaint, Rebiotix requested that the BLA receive accelerated approval and priority review.

168. As shown in Paragraphs 147–153 of the Counterclaims, the use and/or administration of RBX2660 infringes each and every limitation of at least claim 1 of the '012 patent, either literally and/or under the doctrine of equivalents.

169. Rebiotix has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States RBX2660 in the event that the FDA approves

Rebiotix's BLA. Because the use and/or administration of RBX2660 practices the claimed method, an actual and immediate controversy exists regarding Rebiotix's infringement of the '012 patent under 35 U.S.C. § 271.

170. RBX2660, when offered for sale, sold, and/or when used as directed, would be used in a manner that would directly infringe at least claim 1 of the '012 patent either literally and/or under the doctrine of equivalents.

171. The use of RBX2660 constitutes a material part of at least claim 1 of the '012 patent. Rebiotix knows that RBX2660 is especially made or adapted for use in manner that infringes at least claim 1 of the '012 patent, either literally and/or under the doctrine of equivalents and that RBX2660 is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

172. Thus, the offering to sell or sale of RBX2660 would contributorily infringe at least claim 1 of the '012 patent, either literally and/or under the doctrine of equivalents.

173. Rebiotix had knowledge of the '012 patent and, by the information it provides with RBX2660, knows or should know that it will aid and abet another's direct infringement of at least claim 1 of the '012 patent, either literally and/or under the doctrine of equivalents.

174. The manufacture, offering to sell, or sale of RBX2660 by Rebiotix would actively induce infringement of at least claim 1 of the '012 patent, either literally and/or under the doctrine of equivalents.

175. Rebiotix will perform these affirmative acts with knowledge of the '012 patent and with the intent, or willful blindness, that the acts directly infringe the '012 patent. In filing the present Declaratory Judgment action, Rebiotix cited extensively to Finch's S-1 filing, which not only discusses the Sadowsky family generally, but also specifically calls out the '012 patent.

176. Rebiotix's acts of infringement have caused, and unless restrained and enjoined, will continue to cause irreparable injury and damage to Finch/UMN for which there is no adequate remedy at law.

177. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Finch/UMN's reasonable attorney fees.

COUNT 7: INFRINGEMENT OF U.S. PATENT NO. 10,328,107

178. Finch/UMN reallege paragraphs 1–177 as if fully set forth herein.

179. Claim 1 of the '107 patent recites:

> A method comprising:
>
> [a] receiving at a central location a non-frozen stool sample from a donor,
>
> [b] wherein the stool sample is within a stool collection device;
>
> [c] testing the stool sample for pathogens;
>
> [d] mixing the stool sample with a cryoprotectant to form a mixture; and
>
> [e] homogenizing the mixture to produce a composition comprising viable bacteria from the stool sample.

180. RBX2660 is manufactured by receiving from a donor a non-frozen stool sample contained within a human stool collection container with a lid and a large closeable/sealable bag, *see* ¶¶49–53 of the Counterclaims, as required by elements (a) and (b) of claim 1 of the '107 patent, respectively.

181. The material used to manufacture RBX2660 is tested for at least *C. difficile* toxin, norovirus, rotavirus, adenovirus, ova and parasites, vancomycin-resistant enterococci, methicillin-resistant Staphylococcus aureus, Vibrios, Listeria, and/or enteric pathogens, *see* ¶¶49–53 of the Counterclaims, as required by element (c) of claim 1 of the '107 patent.

182. Following screening, 50 mg of the human stool received from the donor is added to 150 mL of 0.9% saline and polyethylene glycol 3350, a cryoprotectant, *see* ¶¶49–53 of the Counterclaims, as required by element (d) of claim 1 of the '107 patent.

183. The resulting suspension is homogenized to form a slurry that contains at least 10^7 live organisms/mL, *see* ¶¶49–53 of the Counterclaims, as required by element (e) of claim 1 of the '107 patent.

184. Thus, the manufacture of RBX2660 will meet each and every limitation of at least claim 1 of the '107 patent, either literally and/or under the doctrine of equivalents.

185. Based on the facts alleged in the Complaint, Rebiotix previously provided RBX2660 to patients under the FDA's enforcement discretion policy. On information and belief, these activities are, at least in part, for commercial purposes, and hence are not "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." 35 U.S.C. § 271(e)(1). At least these activities are thus not protected by the provisions of 35 U.S. Code § 271(e)(1).

186. Because RBX2660 is manufactured using the claimed method, such use of RBX2660 in patients shows that Rebiotix is practicing the claimed method and thus using Finch's patented technology. Accordingly, an actual and immediate controversy exists regarding Rebiotix's infringement of the '107 patent under 35 U.S.C. § 271.

187. Rebiotix's manufacture, use, offer to sell, or sale of RBX2660 in the United States during the term of the '107 patent infringes at least one claim of the '107 patent under 35 U.S.C. § 271.

188. Rebiotix has performed and continues to perform these affirmative acts with knowledge of the '107 patent and with the intent, or willful blindness, that the acts directly infringe the '107 patent. Rebiotix filed the present Declaratory Judgment action, which includes the '107 patent, and in its Complaint, Rebiotix cited extensively to Finch's S-1 filing, which not only discusses Finch's diverse patent portfolio generally, but also specifically calls out the '107 patent.

189. Rebiotix's acts of infringement have caused damage to Finch/UMN, and Finch/UMN are entitled to recover from Rebiotix the damages they have sustained as a result of Rebiotix's wrongful acts in an amount subject to proof at trial.

190. Rebiotix's acts of infringement have caused, and unless restrained and enjoined, will continue to cause irreparable injury and damage to Finch/UMN for which there is no adequate remedy at law.

191. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Finch/UMN's reasonable attorney fees.

COUNT 8: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 10,328,107

192. Finch/UMN reallege paragraphs 1–191 as if fully set forth herein.

193. Based on the facts alleged in the Complaint, Rebiotix completed rolling submission of its BLA seeking regulatory approval to market and sell RBX2660. Based on the facts alleged in the Complaint, Rebiotix requested that the BLA receive accelerated approval and priority review.

194. As shown in Paragraphs 179–184 of the Counterclaims, Rebiotix's method of making RBX2660 infringes each and every limitation of at least claim 1 of the '107 patent, either literally and/or under the doctrine of equivalents.

195. Rebiotix has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States RBX2660 in the event that the FDA approves

Rebiotix's BLA. Because RBX2660 is manufactured by Rebiotix practicing the claimed method, an actual and immediate controversy exists regarding Rebiotix's infringement of the '107 patent under 35 U.S.C. § 271.

196. Rebiotix's manufacture, offer to sell, or sale of the RBX2660 in the United States during the term of the '107 patent would infringe at least one claim of the '107 patent under 35 U.S.C. § 271.

197. Rebiotix will perform these affirmative acts with knowledge of the '107 patent and with the intent, or willful blindness, that the acts directly infringe the '107 patent. Rebiotix filed the present Declaratory Judgment action, which includes the '107 patent, and in its Complaint, Rebiotix cited extensively to Finch's S-1 filing, which not only discusses Finch's diverse patent portfolio generally, but also specifically calls out the '107 patent.

198. Rebiotix's acts of infringement, unless restrained and enjoined, will continue to cause irreparable injury and damage to Finch/UMN for which there is no adequate remedy at law.

199. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Finch/UMN's reasonable attorney fees.

COUNT 9: INFRINGEMENT OF U.S. PATENT NO. 10,463,702

200. Finch/UMN reallege paragraphs 1–199 as if fully set forth herein.

201. Claim 11 of the '702 patent recites:

> [a] An enema delivery system comprising a bag, flexible tubing, and a pharmaceutical composition within the bag,
>
> [b] wherein the pharmaceutical composition is formulated for enema delivery directly from the bag via the flexible tubing,
>
> [c] wherein the pharmaceutical composition comprises saline, polyethylene glycol and the substantially entire microbiota of a stool sample
>
> [d] separated from rough particulate matter of the stool sample,

> [e] wherein the bag comprises an oxygen-resistant material, and
>
> [f] wherein the pharmaceutical composition is in an amount effective for treating recurrence of *C. difficile* infection.

202. Each dose of RBX2660 is contained in a single-dose ready-to-use 250 mL enema bag with flexible tubing for delivery, *see* ¶¶49–53 of the Counterclaims, as required by elements (a) and (b) of claim 11 of the '702 patent.

203. Each dose of RBX2660 consists of 50 g of human stool and 150 mL 0.9% saline and polyethylene glycol 3350, *see* ¶¶49–53 of the Counterclaims, as required by element (c) of claim 11 of the '702 patent.

204. In manufacturing RBX2660, the stool and saline/cryoprotectant vehicle is blended to form a slurry, which is then filtered to remove insoluble particulate matter, which includes rough particulate matter, *see* ¶¶49–53 of the Counterclaims, as required by element (d) of claim 11 of the '702 patent.

205. Each dose of RBX2660 is contained in an ethylene vinyl acetate enema bag, where ethylene vinyl acetate is an oxygen-resistant material, *see* ¶¶49–53 of the Counterclaims, as required by element (e) of claim 11 of the '702 patent.

206. Rebiotix has reported that RBX2660 is at least 87% effective in patients with recurrent CDI, *see* ¶¶49–53 of the Counterclaims, as required by element (f) of claim 11 of the '702 patent.

207. Thus, RBX2660 will meet each and every limitation of at least claim 11 of the '702 patent, either literally and/or under the doctrine of equivalents.

208. Based on the facts alleged in the Complaint, Rebiotix previously provided RBX2660 to patients under the FDA's enforcement discretion policy. On information and belief, these activities are, at least in part, for commercial purposes, and hence are not "solely for uses

reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." 35 U.S.C. § 271(e)(1). At least these activities are thus not protected by the provisions of 35 U.S. Code § 271(e)(1).

209. Because RBX2660 is manufactured using the claimed method, such use of RBX2660 in patients shows that Rebiotix is practicing the claimed method and thus using Finch's patented technology. Accordingly, an actual and immediate controversy exists regarding Rebiotix's infringement of the '702 patent under 35 U.S.C. § 271.

210. Rebiotix's manufacture, use, offer to sell, or sale of RBX2660 in the United States during the term of the '702 patent infringes at least one claim of the '702 patent under 35 U.S.C. § 271.

211. Rebiotix has performed and continues to perform these affirmative acts with knowledge of the '702 patent and with the intent, or willful blindness, that the acts directly infringe the '702 patent. Rebiotix filed the present Declaratory Judgment action, which includes the '702 patent, and in its Complaint, Rebiotix cited extensively to Finch's S-1 filing, which discusses Finch's diverse patent portfolio. In its Complaint, Rebiotix specifically identifies the filing timeline and issuance date of the '702 patent.

212. Rebiotix's acts of infringement have caused damage to Finch/UMN, and Finch/UMN are entitled to recover from Rebiotix the damages they have sustained as a result of Rebiotix's wrongful acts in an amount subject to proof at trial.

213. Rebiotix's acts of infringement have caused, and unless restrained and enjoined, will continue to cause irreparable injury and damage to Finch/UMN for which there is no adequate remedy at law.

214. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Finch/UMN's reasonable attorney fees.

COUNT 10: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 10,463,702

215. Finch/UMN reallege paragraphs 1–214 as if fully set forth herein.

216. Based on the facts alleged in the Complaint, Rebiotix completed rolling submission of the Rebiotix's BLA seeking regulatory approval to market and sell RBX2660. Based on the facts alleged in the Complaint, Rebiotix requested that the BLA receive accelerated approval and priority review.

217. As shown in Paragraphs 201–207 of the Counterclaims, RBX2660 will infringe each and every limitation of at least claim 11 of the '702 patent, either literally and/or under the doctrine of equivalents.

218. Rebiotix has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States RBX2660 in the event that the FDA approves Rebiotix's BLA. Because RBX2660 is manufactured by Rebiotix practicing the claimed method, an actual and immediate controversy exists regarding Rebiotix's infringement of the '702 patent under 35 U.S.C. § 271.

219. Rebiotix's manufacture, offer to sell, or sale of RBX2660 in the United States during the term of the '702 patent would infringe at least one claim of the '702 patent under 35 U.S.C. § 271.

220. Rebiotix will perform these affirmative acts with knowledge of the '702 patent and with the intent, or willful blindness, that the acts directly infringe the '702 patent. Rebiotix filed the present Declaratory Judgment action, which includes the '702 patent, and in its Complaint, Rebiotix cited extensively to Finch's S-1 filing, which discusses Finch's diverse patent portfolio.

In its Complaint, Rebiotix specifically identifies the filing timeline and issuance date of the '702 patent.

221. Rebiotix's acts of infringement, unless restrained and enjoined, will continue to cause irreparable injury and damage to Finch/UMN for which there is no adequate remedy at law.

222. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Finch/UMN's reasonable attorney fees.

COUNT 11: INFRINGEMENT OF U.S. PATENT NO. 10,675,309

223. Finch/UMN reallege paragraphs 1–222 as if fully set forth herein.

224. Claim 12 of the '309 patent recites:

> [a] An enema product configured for transporting to a remote facility,
>
> [b] the enema product comprising flexible tubing, a sealed bag, and a pharmaceutical composition within the bag,
>
> [c] wherein the pharmaceutical composition is formulated for enema delivery from the bag,
>
> [d] wherein the pharmaceutical composition comprises saline, a cryoprotectant and a suspension of viable non-pathogenic fecal bacteria,
>
> [e] wherein the fecal bacteria are from a stool of a human donor,
>
> [f] wherein the fecal bacteria are separated from rough particulate matter and are not cultured, and
>
> [g] wherein the pharmaceutical composition is in an amount effective for treating recurrence of *C. difficile* infection.

225. RBX2660 is an enema delivery system that is configured and stored at the manufacturer for transport to a remote clinical site, *see* ¶¶43–47 of the Counterclaims, as required by element (a) of claim 12 of the '309 patent.

226. Each dose of RBX2660 is contained in a single-dose ready-to-use sealed 250 mL enema bag with flexible tubing for delivery, *see* ¶¶43–47 of the Counterclaims, as required by elements (b) and (c) of claim 12 of the '309 patent.

227. Each dose of RBX2660 contains at least 10^7 live organisms/mL of suspension and consists of 50 g of human stool collected from a pre-screened, healthy donor and 150 mL 0.9% saline and polyethylene glycol 3350, a cryoprotectant, *see* ¶¶43–47 of the Counterclaims, as required by elements (d) and (e) of claim 12 of the '309 patent.

228. In manufacturing RBX2660, the stool from a human donor and saline/cryoprotectant vehicle is blended to form a slurry, which is then filtered to separate the non-cultured fecal bacteria from insoluble particulate matter, which includes rough particulate matter, *see* ¶¶43–47 of the Counterclaims, as required by element (f) of claim 12 of the '309 patent.

229. Rebiotix has reported that RBX2660 is at least 87% effective in patients with recurrent CDI, *see* ¶¶43–47 of the Counterclaims, as required by element (g) of claim 12 of the '309 patent.

230. Thus, RBX2660 will meet each and every limitation of at least claim 12 of the '309 patent, either literally and/or under the doctrine of equivalents.

231. Based on the facts alleged in the Complaint, Rebiotix previously provided RBX2660 to patients under the FDA's enforcement discretion policy. On information and belief, these activities are, at least in part, for commercial purposes, and hence are not "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." 35 U.S.C. § 271(e)(1). At least these activities are thus not protected by the provisions of 35 U.S. Code § 271(e)(1).

232. Because RBX2660 is manufactured using the claimed method, such use of RBX2660 in patients shows that Rebiotix is practicing the claimed method and thus using Finch's patented technology. Accordingly, an actual and immediate controversy exists regarding Rebiotix's infringement of the '309 patent under 35 U.S.C. § 271.

233. Rebiotix's manufacture, use, offer to sell, or sale of the RBX2660 in the United States during the term of the '309 patent infringes at least one claim of the '309 patent under 35 U.S.C. § 271.

234. Rebiotix has performed and continues to perform these affirmative acts with knowledge of the '309 patent and with the intent, or willful blindness, that the acts directly infringe the '309 patent. Rebiotix filed the present Declaratory Judgment action, which includes the '309 patent, and in its Complaint, Rebiotix cited extensively to Finch's S-1 filing, which discusses Finch's diverse patent portfolio. In its Complaint, Rebiotix specifically identifies the filing timeline and issuance date of the '309 patent.

235. Rebiotix's acts of infringement have caused damage to Finch/UMN, and Finch/UMN are entitled to recover from Rebiotix the damages they have sustained as a result of Rebiotix's wrongful acts in an amount subject to proof at trial.

236. Rebiotix's acts of infringement have caused, and unless restrained and enjoined, will continue to cause irreparable injury and damage to Finch/UMN for which there is no adequate remedy at law.

237. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Finch/UMN's reasonable attorney fees.

COUNT 12: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 10,675,309

238. Finch/UMN reallege paragraphs 1–237 as if fully set forth herein.

239. Based on the facts alleged in the Complaint, Rebiotix completed rolling submission of the Rebiotix's BLA seeking regulatory approval to market and sell RBX2660. Based on the facts alleged in the Complaint, Rebiotix requested that the BLA receive accelerated approval and priority review.

240. As shown in Paragraphs 224–230 of the Counterclaims, RBX2660 will infringe each and every limitation of at least claim 12 of the '309 patent, either literally and/or under the doctrine of equivalents.

241. Rebiotix has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States RBX2660 in the event that the FDA approves Rebiotix's BLA. Because RBX2660 is manufactured by Rebiotix practicing the claimed method, an actual and immediate controversy exists regarding Rebiotix's infringement of the '309 patent under 35 U.S.C. § 271.

242. Rebiotix's manufacture, offer to sell, or sale of the RBX2660 in the United States during the term of the '309 patent would infringe at least one claim of the '309 patent under 35 U.S.C. § 271.

243. Rebiotix will perform these affirmative acts with knowledge of the '309 patent and with the intent, or willful blindness, that the acts directly infringe the '309 patent. Rebiotix filed the present Declaratory Judgment action, which includes the '309 patent, and in its Complaint, Rebiotix cited extensively to Finch's S-1 filing, which discusses Finch's diverse patent portfolio. In its Complaint, Rebiotix specifically identifies the filing timeline and issuance date of the '309 patent.

244. Rebiotix's acts of infringement, unless restrained and enjoined, will continue to cause irreparable injury and damage to Finch/UMN for which there is no adequate remedy at law.

245. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Finch/UMN's reasonable attorney fees.

PRAYER FOR RELIEF

WHEREFORE, Finch/UMN respectfully request that this Court enter a Judgment and Order against Rebiotix as follows:

A. Dismissing Rebiotix's Complaint, including each of Rebiotix's declaratory judgment claims, with prejudice and in their entirety;

B. Entering a judgment and declaration against Rebiotix and in favor of Finch/UMN in all respects, including that Rebiotix has and will continue to infringe at least one claim of the '914, '011, '012,'107, '702, and '309 patents;

C. For an order permanently enjoining Rebiotix, and their respective officers, directors, shareholders, agents, servants, employees, attorneys, all parent, subsidiary and affiliate corporations, their successors in interest and assigns, and all other entities and individuals acting in concert with it or on its behalf, including customers, from making, importing, using, offering for sale, and/or selling any product or service falling within the scope of any claim of the '914, '011, '012, '107, '702, and '309 patents, including RBX2660, or otherwise infringing any claim of the '914, '011, '012, '107, '702, and '309 patents;

D. Alternatively, in the event that an injunction does not issue, that this Court award a compulsory ongoing future royalty;

E. For damages arising from Rebiotix's infringement of the '914, '011, '012, '107, '702, and '309 patents, including lost profits suffered as a result of Rebiotix's infringement and in an amount not less than a reasonable royalty, together with pre-judgment and post-judgment interest;

F. That this Court declare Rebiotix's infringement to be willful and award increased damages in an amount not less than three times the damages assessed for Rebiotix's infringement for the period of such willful infringement pursuant to 35 U.S.C.§ 284;

G. Entering a judgment that this is an exceptional case and an award of reasonable attorney's fees pursuant to 35 U.S.C. § 285;

H. Awarding Finch/UMN their costs and expenses; and

I. Granting such other relief as the Court deems just and proper.

JURY DEMAND

Finch/UMN, by and through their undersigned counsel, hereby demand, pursuant to Fed. R. Civ. P. 38, a trial by jury on all claims so triable in this action.

ANSWER TO COMPLAINT

Each of the paragraphs below corresponds to the same-numbered paragraphs in the Complaint. Finch denies all allegations in the Complaint, whether express or implied, that are not specifically admitted below. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications, or speculations that arguably follow from the admitted facts. Finch denies that Plaintiffs are entitled to the relief requested or any other relief.

Finch, through its undersigned attorneys, answers as follows:

THE PARTIES

1. Plaintiff Ferring is a private Delaware corporation having its principal place of business at 100 Interpace Parkway, Parsippany, New Jersey 07054.

ANSWER: Finch admits upon information and belief, based on the facts alleged in the Complaint, that Ferring Pharmaceuticals Inc. is a private Delaware corporation having its principal place of business at 100 Interpace Parkway, Parsippany, New Jersey 07054.

2. Plaintiff Rebiotix, a Ferring company is a private Delaware corporation having its principal place of business at 2660 Patton Road, Roseville, Minnesota 55113.

ANSWER: Finch admits upon information and belief, based on the facts alleged in the Complaint, that Rebiotix Inc. is a private Delaware corporation having its principal place of business at 2660 Patton Road, Roseville, Minnesota 55113.

3. On information and belief, Defendant Finch Therapeutics Group, Inc. ("FTG") is a corporation organized and existing under the laws of Delaware, having a principal place of business at 200 Inner Belt Road, Somerville, Massachusetts 02143. On information and belief, FTG was formed in 2017 as a result of a merger and recapitalization of Finch Therapeutics, Inc. and Crestovo Holdings LLC. (Ex. 1 at F-8.) On information and belief, Crestovo Holdings LLC was renamed as Finch Therapeutics Holdings LLC. (*Id.*)

ANSWER: Finch admits that Finch Therapeutics Group, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 200 Inner Belt Road, Suite 400, Somerville, Massachusetts 02143. Finch Therapeutics Group, Inc. conducted business through Finch Therapeutics, Inc. until September 21, 2017. Pursuant to a merger agreement dated September 21, 2017, Finch Therapeutics, Inc. and Crestovo Holdings LLC completed a merger of equals, where both Finch Therapeutics, Inc. and Crestovo Holdings LLC survived the merger as wholly-owned subsidiaries of Finch Therapeutics Group, Inc. Finch admits that Crestovo Holdings LLC was renamed Finch Therapeutics Holdings LLC in November 2020. Finch denies any remaining allegations set forth in Paragraph 3 of the Complaint.

4. On information and belief, Defendant Finch Therapeutics, Inc. ("FTI") is a corporation organized and existing under the laws of Delaware, having a principal place of business at 200 Inner Belt Road, Somerville, MA 02143. On information and belief, FTI is a wholly-owned subsidiary of Finch Therapeutics Group, LLC.

ANSWER: Finch admits that Finch Therapeutics, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 200 Inner Belt Road, Suite 400, Somerville, MA 02143. Finch admits that Finch Therapeutics, Inc. is a wholly-owned

subsidiary of Finch Therapeutics Group, Inc. Finch denies any remaining allegations set forth in Paragraph 4 of the Complaint.

5. On information and belief, Defendant Finch Therapeutics Holding LLC ("FTH") is a corporation organized and existing under the laws of Delaware, having a principal place of business at 200 Inner Belt Road, Somerville, MA 02143. On information and belief, FTH is a wholly-owned subsidiary of FTG.

ANSWER: Finch admits that Finch Therapeutics Holdings LLC is a Delaware limited liability company having a principal place of business at 200 Inner Belt Road, Suite 400, Somerville, MA 02143. Finch admits that Finch Therapeutics Holdings LLC is a wholly-owned subsidiary of Finch Therapeutics Group, Inc. Finch denies any remaining allegations set forth in Paragraph 5 of the Complaint.

NATURE OF THE ACTION

6. This is an action seeking a declaratory judgment that the claims of United States Patents Number 10,675,309 ("the '309 patent") (Ex. 2), United States Patent No. 10,463,702 ("the '702 patent") (Ex. 3), United States Patent Number 10,328,107 ("the '107 patent") (Ex. 4), United States Patent Number 10,064,899 ("the '899 patent") (Ex. 5), United States Patent Number 10,022,406 ("the '406 patent") (Ex. 6), United States Patent Number 9,962,413 ("the '413 patent") (Ex. 7), and United States Patent Number 9,308,226 ("the '226 patent") (Ex. 8) (collectively, the "patents in suit") are invalid or not infringed.

ANSWER: Finch states that the allegations set forth in Paragraph 6 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Finch admits that Plaintiffs purport to seek a declaratory judgment that the claims of United States Patent Nos. 10,675,309 ("the '309 patent"), 10,463,702 ("the '702 patent"), 10,328,107 ("the '107 patent"), 10,064,899 ("the '899 patent"), 10,022,406 ("the '406 patent"), 9,962,413 ("the '413 patent"), and 9,308,226 ("the '226 patent") (collectively, the "Patents-in-Suit") are invalid or not infringed. Finch denies any remaining allegations set forth in Paragraph 6 of the Complaint.

7. This action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202 and the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

ANSWER: Finch states that the allegations set forth in Paragraph 7 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Finch denies the same.

8. Plaintiffs are seeking United States Food and Drug Administration ("FDA") approval for a new product, designated RBX2660. RBX2660 is an enema preparation containing a liquid suspension of a diverse consortium of fecal microorganisms. To produce the suspension, fecal samples are collected from pre-screened, healthy donors then blended with a solution consisting of saline and polyethylene glycol ("PEG") to form a slurry. The slurry is then filtered to remove some of the insoluble particulate matter. The suspension is then delivered as a single-dose, ready-to-use enema in a general practitioner's office, or in a clinical or hospital setting. RBX2660 will be indicated for reduce the recurrence of *Clostridium difficile* infection ("CDI") in adults following antibiotic treatment for first or more recurrence of CDI. Recurrence of CDI is also known as "recurrent CDI" ("rCDI").

ANSWER: Finch admits upon information and belief, based on the facts alleged in the Complaint, that Plaintiffs are seeking FDA approval for RBX2660, an enema preparation containing fecal microorganisms. Finch admits that Rebiotix's publically available materials describe RBX2660 in this manner, as described further above at Paragraphs 49–53 of the Counterclaims. Finch admits that *Clostridium difficile* infection is sometimes abbreviated as "CDI" and recurrent CDI as "rCDI". Otherwise, Finch lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 8 of the Complaint and, therefore, denies the same.

9. Plaintiffs are seeking a declaratory judgment that the patents in suit are invalid and that RBX2660, once approved by the FDA and sold, will not infringe any valid claims of the patents in suit.

ANSWER: Finch states that the allegations set forth in Paragraph 9 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Finch denies the same.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Finch states that the allegations set forth in Paragraph 10 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Finch does not contest that this court has jurisdiction over the subject matter of this action for the purposes of the patents asserted in Finch's Counterclaims, but denies that subject matter jurisdiction exists for the patents that are not named in Finch's Counterclaims. Finch denies the remaining allegations set forth in Paragraph 10 of the Complaint.

11. On information and belief, this Court has personal jurisdiction over FTG. On information and belief, FTG is organized under the laws of the State of Delaware and is registered to conduct business within the State of Delaware (File No. 6547340). (*See* Ex. 9.) On information and belief, FTG maintains a registered agent for service of process in Delaware.

ANSWER: Finch admits that Finch Therapeutics Group, Inc. is a Delaware corporation and is registered to conduct business within the State of Delaware. Finch admits that Finch Therapeutics Group, Inc. maintains a registered agent for service of process in Delaware. Finch states that the remaining allegations set forth in Paragraph 11 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Finch does not contest personal jurisdiction for the purposes of the instant action only. Finch denies the remaining allegations set forth in Paragraph 11 of the Complaint.

12. On information and belief, this Court has personal jurisdiction over FTI. On information and belief, FTI is organized under the laws of the State of Delaware and is registered to conduct business within the State of Delaware (File No. 5638942). (*See* Ex. 10.) On information and belief, FTI maintains a registered agent for service of process in Delaware.

ANSWER: Finch admits that Finch Therapeutics, Inc. is a Delaware corporation and is registered to conduct business within the State of Delaware. Finch admits that Finch Therapeutics, Inc. maintains a registered agent for service of process in Delaware. Finch states that the remaining allegations set forth in Paragraph 12 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Finch does not contest

personal jurisdiction for the purposes of the instant action only. Finch denies the remaining allegations set forth in Paragraph 12 of the Complaint.

13. On information and belief, this Court has personal jurisdiction over FTH. On information and belief, FTH is organized under the laws of the State of Delaware and is registered to conduct business within the State of Delaware (File No. 6310412). (*See* Ex. 11.) On information and belief, FTH maintains a registered agent for service of process in Delaware.

ANSWER: Finch admits that Finch Therapeutics Holdings LLC is a Delaware limited liability company and is registered to conduct business within the State of Delaware. Finch admits that Finch Therapeutics Holdings LLC maintains a registered agent for service of process in Delaware. Finch states that the remaining allegations set forth in Paragraph 13 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Finch does not contest personal jurisdiction for the purposes of the instant action only. Finch denies the remaining allegations set forth in Paragraph 13 of the Complaint.

14. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c) because Defendants are incorporated in Delaware.

ANSWER: Finch admits that Finch Therapeutics Group, Inc., Finch Therapeutics, Inc., and Finch Therapeutics Holdings LLC are organized under the laws of Delaware. The remaining allegations set forth in Paragraph 14 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Finch does not contest that venue is proper in this District for the purposes of the instant action only. Finch denies the remaining allegations set forth in Paragraph 14 of the Complaint.

OVERVIEW OF FECAL MICROBIOTA TRANSPLANT THERAPY

15. A typical healthy human gut contains a host of symbiotic microorganisms known as the normal flora (or "microbiota"). The microbiota of a healthy individual is extremely important, as it aids in digestion, stimulates the immune system, modulates energy metabolism, and helps to modulate the growth of opportunistic or "bad" microorganisms. In some situations, the normal microbiota can become disrupted or compromised. For example, use of antibiotics can substantially decrease the gut microbiota, leaving the gut susceptible to rampant overgrowth of pathogenic organisms, including *Clostridium difficile* ("*C. difficile*").

ANSWER: Human flora is an important virtual organ containing large numbers of living organisms and when key microbes are lost, the resulting dysbiosis is believed to increase susceptibility to immune disorders, infections, neurological conditions, cancer and other serious diseases. Treatment with antibiotics can reduce microbiome diversity and the resulting dysbiosis may result in *Clostridium difficile* ("*C. difficile*") infection ("CDI"). Finch denies any remaining allegations set forth in Paragraph 15 of the Complaint.

16. *C. difficile* was first isolated in 1935. It was not until 1978, however, that scientists recognized that CDI was associated with human disease and that *C. difficile* was responsible for the majority of cases of antibiotic-associated diarrhea. (Ex. 12 at 1.) *C. difficile* produces two toxins, known as toxin A and toxin B, that cause intestinal inflammation. This inflammation may lead to nausea, diarrhea, colitis, kidney failure, and even death. The incidence of CDI has been increasing over the course of the last twenty years as a result of a more virulent strain of the bacteria that became more prevalent in the early 2000's.

ANSWER: *C. difficile*, is a toxin-producing, spore-forming bacterium that causes severe and persistent diarrhea in infected individuals. *C. difficile* expresses toxins that lead to inflammation of the colon, severe diarrhea and abdominal pain, as well as potentially more serious clinical outcomes including toxic megacolon, perforation of the colon, and death. Disruption of the gut microbiome is associated with a large number of diseases that have dramatically increased in prevalence among populations in developed countries over the past century. Finch is without sufficient information to admit or deny the remaining allegations and on that basis denies any remaining allegations set forth in Paragraph 16 of the Complaint.

17. In a February 25, 2015 press release, the United States Centers for Disease Control and Prevention ("CDC") released information regarding a 2011 CDC study into CDI in the United States. (Ex. 13 at 1.) According to the study, CDI infects approximately 500,000 people per year and approximately 29,000 people died within thirty (30) days of the initial diagnosis, with about 15,000 of those deaths directly attributable to CDI. (*Id.*) According to the study, one out of every eleven patients aged sixty-five or older with a healthcare-associated CDI died within thirty (30) days of diagnosis. (*Id.*) With respect to recurrence, the study also found that one out of every five patients with a healthcare-associated CDI had at least one recurrence. (*Id.*)

ANSWER: Finch admits that Exhibit 13 to the Complaint appears to be a press release from the CDC Newsroom titled "Nearly half a million Americans suffered from *Clostridium difficile* infections in a single year." Finch admits that Exhibit 13 to the Complaint states that "[a]pproximately 29,000 patients died within 30 days of the initial diagnosis of *C. difficile*. Of those, about 15,000 deaths were estimated to be directly attributable to *C. difficile* infections, making *C. difficile* a very important cause of infectious disease death in the United States." D.I. 1, Ex. 13 at 1. Finch admits that Exhibit 13 to the Complaint states that "1 out of every 5 patients with a healthcare-associated *C. difficile* infection experienced a recurrence of the infection and 1 out of every 11 patients aged 65 or older with a healthcare-associated *C. difficile* infection died within 30 days of diagnosis." *Id.* Finch denies any remaining allegations set forth in Paragraph 17 of the Complaint.

18. In 2013, the CDC identified *C. difficile* as one of three bacteria that represented an urgent threat that required "urgent public health attention to identify infections and to limit transmission"). (Ex. 14 at 21.) In 2019, the CDC's updated Antibiotic Resistance Threats in the United States continued to list *C. difficile* as an urgent threat, noting that "nearly 223,900 people in the United States required hospital care for *C. difficile* and at least 12,800 people died in 2017." (Ex. 15 at vii, *see also id.* at 3.) The estimated healthcare costs attributable to CDI in the United States in 2017 was approximately $1,000,000,000.00. (*Id.* at 81 of 150.)

ANSWER: Finch admits that Exhibits 14 and 15 to the Complaint appear to be publications by the Centers for Disease Control and Prevention ("CDC"). Finch admits that Exhibit 14 states that certain threats, including *C. difficile* "may not be currently widespread but have the potential to become so and require urgent public health attention to identify infections and to limit transmission." Ex. 14 at 21. Finch admits that Exhibit 15 states that "nearly 223,900 people in the United States required hospital care for *C. difficile* and at least 12,800 people died in 2017." Ex. 15 at vii. Finch admits that Exhibit 15 reports $1 billion "estimated attributable healthcare costs in 2017." Ex. 15 at 82 of 151. Finch denies any remaining allegations set forth in Paragraph 18 of the Complaint.

19. CDI can be treated by the administration of antibiotics, including metronidazole or vancomycin. In many cases, however, because the normal microbiota is compromised, it is incapable of inhibiting growth of *C. difficile* following the antibiotic regimen. As a result, the *C. difficile* population outcompetes other organisms, resulting in rCDI.

ANSWER: CDI has been treated by administration of antibiotics, though this is an imperfect treatment. The leading CDI antibiotic, vancomycin, is non-specific and causes significant disruption to the microbiome. Fidaxomicin was designed as an alternative, narrow-spectrum antibiotic, with reduced activity against other microbes. While this microbiome-sparing approach can reduce further damage to the microbiome, it does not restore the missing microbes eliminated by previous antibiotic exposure. When an antibiotic course is complete, the residual *C. difficile* spores can germinate into vegetative, toxin-producing *C. difficile*, driving CDI recurrence, a key driver of morbidity, mortality and cost in CDI care. Finch denies any remaining allegations set forth in Paragraph 19 of the Complaint.

20. Recognizing that disruptions of a normal microbiota impacted the health of individuals, a group of researchers from the Department of Surgery and Medicine, University of Colorado School of Medicine, and the Veterans Administration Hospital, led by Dr. B. Eiseman, attempted to restore the gut microbiota in patients by administering the first fecal transplants in humans recorded in the literature in 1958. (*See* Ex. 16 at 859.) Dr. Eiseman utilized a retention enema composed of "normal feces" from a healthy donor suspended in saline. The recipients of these fecal transplants were observed to experience a "marked improve[ment]", and he recommended that treatment should be further evaluated. (*Id*.)

ANSWER: Finch admits that Exhibit 16 appears to be a publication titled "Fecal Enema as an Adjunct in the Treatment of Pseudomembranous Enterocolitis," authored by B. Eiseman and others from the Departments of Surgery and Medicine at the University of Colorado School of Medicine and the Veterans Administration Hospital, and states that it was "[r]eceived for publication" June 23, 1958. Finch admits that Rebiotix has attempted to paraphrase Exhibit 16 and that the document includes discussion of fecal transplants. Finch is without sufficient information to admit or deny the remaining allegations and on that basis denies any remaining allegations set forth in Paragraph 20 of the Complaint.

21. In 1981, Dr. Talmadge Bowden and his team from the Medical College of Georgia and the University of Maryland expanded on the early work of Dr. Eiseman and identified *C. difficile* as the cause of a variety of gastrointestinal problems. (*See, e.g.*, Ex. 17 at 178.) Following the lead of Dr. Eiseman, Dr. Bowden successfully treated the gastrointestinal disorders through restoration of fecal floral homeostasis with "fresh fecal solution" installed through an enema. (*Id.* at 182-83.)

ANSWER: Finch admits that Exhibit 17 appears to be an article titled "Pseudomembraneous Enterocolitis: Mechanism of Restoring Floral Homeostasis" authored by Talmadge A. Bowden and others from the Department of Surgery, Section of Gastrointestinal Surgery and Surgical Endoscopy Unit at the Medical College of Georgia and the Department of Surgery at the University of Maryland, and published in the American Surgeon in April 1981. Finch admits Rebiotix has attempted to paraphrase Exhibit 17 and that the document includes discussion of fecal transplants. Finch is without sufficient information to admit or deny the remaining allegations and on that basis denies any remaining allegations set forth in Paragraph 21 of the Complaint.

22. Following the successful fecal transplant procedures of Drs. Eiseman and Bowden, researchers began to focus more narrowly on the use of fecal microbiota transplant ("FMT") therapy. For example, in 1998, Dr. Stein Lund-Tonnesen from Stockholm, Sweden successfully applied the methods of Drs. Eiseman and Bowden by treating a significant number of patients suffering from CDI with FMT. As described in an article titled "Clostridium difficile-associated diarrhea treated with homologous feces," Journal of Norwegian Medical Association No. 7, (1998) (Ex. 18 (original Swedish publication) and Ex. 19 (certified English translation)), Dr. Lund-Tonnesen and his team collected fecal samples from pre-screened individuals and diluted the samples with milk. (Ex. 19 at 4, 6.) The slurry was then homogenized and filtered through gauze to ensure easy installation through the narrow biopsy channel of a colonoscope. (*Id.* at 4.) The samples consisted of 20 mL syringes, each containing 5-10 grams of processed feces. (*Id.* at 4.) The syringes with the fecal preparation were frozen at -20 °C and then thawed prior to use. (*Id.* at 4.)

ANSWER: Finch admits that Exhibit 19 appears to be a translation of an article titled "Clostridium difficile-associated diarrhea treated with homologous feces," authored by Stein Lund-Tønnesen and others, published in the Journal of the Norwegian Medical Association in 1998. Finch admits that Rebiotix has attempted to paraphrase Exhibit 19 and that the document

includes discussion of fecal preparations. Finch denies any remaining allegations set forth in Paragraph 22 of the Complaint.

23. In 2009, Dr. Johan Bakken from St. Luke's Hospital, Infectious Disease Associates, in Duluth, Minnesota, added to the growing field of FMT by treating a pool of one hundred patients suffering from rCDI with FMT. Dr. Bakken's work is described in an article titled "Fecal bacteriotherapy for recurrent *Clostridium difficile* infection," Anaerobe 15 (2009) (Ex. 20). As described in the article, Dr. Bakken collected samples from donors, and pre-screened the samples for contagious agents. (*Id.* at 286-87.) Saline or milk was added as a diluent or diluent/cryoprotectant, respectively, for liquefying the stool samples and protecting the organisms during freezing. (*Id.* at 287.) The samples were subsequently homogenized and filtered through gauze or a coffee filter to remove particulate matter. (*Id.* at 287.) The stool slurry was administered (either fresh or after freezing/thawing) through an enema or by nasogastric or nasojejunal catheter, and successfully treated 89% of the patients that had previously been unresponsive to other forms of rCDI therapy. (*Id.* at 287-88.)

ANSWER: Finch admits that Exhibit 20 appears to be an article titled "Fecal bacteriotherapy for recurrent Clostridium difficile infection," authored by Johan S. Bakken, in the journal Anaerobe in 2009. Finch admits that Rebiotix has attempted to paraphrase Exhibit 20 and that the document includes discussion of fecal bacteriotherapy. Finch denies any remaining allegations set forth in Paragraph 23 of the Complaint.

THE DEVELOPMENT OF RBX2660

24. Between 2008 and 2010, Dr. Edwin Hlavka made additional advances in FMT. These advances would become the core technology underlying RBX2660 and are described in U.S. Provisional Applications Nos. 61/337,283 (Ex. 21) and 61/351,184 (Ex. 22), filed February 1, 2010 and June 3, 2010, respectively. A PCT application claiming priority to these applications was filed on February 1, 2011, which published on August 4, 2011 as WO 2011/094027. (Ex. 23.) These applications describe a collection of fresh or frozen fecal samples from pre-screened, healthy donors. (*See, e.g.*, Ex. 21 at 3; Ex. 22 at 25-26; Ex. 23 at 4-6.) The PCT application then states that the samples were then homogenized with a combination of saline and a cryoprotectant (including glycol, glycerol, dimethylsulfoxide, dairy milk, or soy milk) and filtered to remove some of the particulate matter from the samples. (*See, e.g.*, Ex. 23 at 13, 18.) The suspension could then be administered by various methods, including by enema, a gastro-resistant capsule, or with a nasogastric tube. (Ex. 23 at 6.) Dr. Hlavka's application describes further narrowing descriptions of the preexisting FMT technology, including administration of oral capsules, and bacteriotherapy banks. (*See, e.g.*, Ex. 23 at 6, 8, Figure 2.)

ANSWER: Finch admits that the first page of Exhibit 21 appears to be a Provisional Application for Patent Cover Sheet filed February 1, 2010, identifying Edwin J. Hlavka as the alleged inventor,

and listing the title of the patent application as "Bacteriotherapy for Clostridium Difficile Colitis." Finch admits that page 2 of Exhibit 22 appears to be a Provisional Application for Patent Cover Sheet filed June 3, 2010, identifying Edwin J. Hlavka as the alleged inventor, and listing the title of the application as "Bacteriotherapy for Clostridium Difficile Colitis." Finch admits that Exhibit 23 appears to be a PCT publication that purports to claim priority to provisional applications 61/337,283 and 61/351,184. Finch admits that Rebiotix has attempted to paraphrase Exhibit 23 and that the document includes discussion of donor fecal samples. Finch is without sufficient information to admit or deny the remaining allegations and on that basis denies any remaining allegations set forth in Paragraph 24 of the Complaint.

25. Rebiotix (formerly MikrobEX, Inc.) was founded in 2011 to further develop the FMT treatments developed by Dr. Hlavka. Rebiotix began developing FMT products to treat patients suffering from certain gastrointestinal disorders, including rCDI.

ANSWER: Finch is without sufficient information to form a belief as to the truth of the allegations set forth in Paragraph 25 of the Complaint and, therefore, denies the same.

26. Rebiotix has invested significant time and expense in order to develop RBX2660. For example, Rebiotix began conversations with the FDA in March 2012 regarding the product that would become RBX2660. This included a request for a pre-Investigational New Drug Application ("pre-IND") meeting in October 2012. The FDA granted the pre-IND meeting request and the meeting was held on January 18, 2013.

ANSWER: Finch is without sufficient information to form a belief as to the truth of the allegations set forth in Paragraph 26 of the Complaint and, therefore, denies the same.

27. Rebiotix submitted its Investigational New Drug Application ("IND") on March 21, 2013 and the FDA assigned the IND number 15439. As part of its development and communication with the FDA, Rebiotix has responded to various requests for information and provided various complete responses, including information regarding its donor screening procedures and clinical trials.

ANSWER: Finch is without sufficient information to form a belief as to the truth of the allegations set forth in Paragraph 27 of the Complaint and, therefore, denies the same.

28. On May 21, 2013, the FDA granted fast track designation status for RBX2660. On March 10, 2014, the FDA granted orphan designation status for RBX2660 for the prevention of recurrent *Clostridium difficile* infection (CDI) in individuals with recurrent *Clostridium difficile* infection. On October 8, 2015, the FDA granted breakthrough therapy designation status for RBX2660.

ANSWER: Finch is without sufficient information to form a belief as to the truth of the allegations set forth in Paragraph 28 of the Complaint and, therefore, denies the same.

29. The clinical development program for RBX2660 is the largest ever conducted in the field of microbiome-based therapeutics. For example, Rebiotix has completed five prospective trials with RBX2660. These trials included three Phase 2 studies (PUNCH CD, PUNCH CD2, PUNCH CD Open Label) and two Phase 3 studies (PUNCH CD3 and PUNCH CD2-OLS ad hoc analysis) and represent over a decade's worth of work and development.

ANSWER: Finch is without sufficient information to form a belief as to the truth of the allegations set forth in Paragraph 29 of the Complaint and, therefore, denies the same.

30. In a September 29, 2021 press release, Ferring and Rebiotix announced the results of the trials, stating that the trials included 723 actively-treated participants and overall showed that up to 78.9% of the participants remained recurrence-free for eight weeks post treatment (which was defined as treatment success). In those participants who did not respond to initial treatment, an optional additional treatment course was administered, resulting in overall rates of treatment success of up to 84.4%. Notably, most primary responders remained free of CDI for six months and up to two years, with a sustained clinical response success rate of up to 92.1% of the Phase 3 program.

ANSWER: Finch is without sufficient information to form a belief as to the truth of the allegations set forth in Paragraph 30 of the Complaint and, therefore, denies the same.

31. In addition to the clinical trials discussed above, Rebiotix previously provided RBX2660 to patients under an FDA enforcement discretion policy allowing for the use of FMT to treat CDI in patients not responding to standard therapies when certain conditions are met. In October 2021, Ferring and Rebiotix, a Ferring Company, presented data from a retrospective analysis at the American College of Gastroenterology 2021 annual scientific meeting. In the analysis, ninety-four (94) participants with comorbid conditions commonly found in people with rCDI were treated with RBX2660. The analysis showed a treatment success rate of 82.8%, with no observable difference between participants who received one dose (83.3%) versus two doses (82.5%).

ANSWER: Finch is without sufficient information to form a belief as to the truth of the allegations set forth in Paragraph 31 of the Complaint and, therefore, denies the same.

32. Paul Feuerstadt, MD, FACG, AGAF of the Yale University School of Medicine stated that "[t]he results of this retrospective study provide critical additional information about RBX2660, as it supports the concept that data observed in well-controlled, prospective clinical trials may be replicable in a real-world setting." (Ex. 24 at 2.) Dr. Feuerstadt further explained that "[t]his research shows that even with wide eligibility criteria, RBX2660 performed similarly to the more narrow and limited inclusion for the Phase 2 and 3 trials. This retrospective study included patients across different comorbidities who are more representative of the population living with *C. difficile* and remain vulnerable to the debilitating cycle of recurrence." (*Id.*)

ANSWER: Finch admits that Exhibit 24 includes the language quoted in Paragraph 32 of the Complaint. Finch denies any remaining allegations set forth in Paragraph 32 of the Complaint.

33. The data from the clinical trials and retrospective analysis of results from use of RBX2660 under the FDA's enforcement discretion policy demonstrate a consistent efficacy and safety profile for RBX2660 that spanned over a decade of work. They reinforce the enormous potential of microbiome-based therapeutics to transform the care of people suffering from rCDI.

ANSWER: Finch is without sufficient information to form a belief as to the truth of the allegations set forth in Paragraph 33 of the Complaint and, therefore, denies the same.

34. On information and belief, Defendants were aware of the clinical trials and use of RBX2660 under the FDA's enforcement discretion policy.

ANSWER: Finch admits that, as a leader in the microbiome field, it is a common practice to be aware of certain developments in the field. Finch denies any remaining allegations set forth in Paragraph 34 of the Complaint.

THE RELATIONSHIP BETWEEN REBIOTIX AND FERRING

35. Ferring is a research-driven specialty biopharmaceutical company committed to helping people around the world build families and live better lives. Ferring is a leader in reproductive medicine and maternal health and in specialty areas of gastroenterology and urology.

ANSWER: Finch is without sufficient information to form a belief as to the truth of the allegations set forth in Paragraph 35 of the Complaint and, therefore, denies the same.

36. Rebiotix was acquired by Ferring Holding Inc. in April 2018. Rebiotix is a late stage clinical microbiome company focused on harnessing the power of the human microbiome to revolutionize the treatment of challenging diseases. With the acquisition of Rebiotix, Ferring is committed to exploring the crucial link between the microbiome and human health, beginning with the treatment of rCDI.

ANSWER: Finch admits that, on information and belief, based on the facts alleged in the Complaint, Rebiotix Inc. was acquired by Ferring Holding Inc. in April 2018. Finch is without sufficient information to form a belief as to the truth of the remaining allegations set forth in Paragraph 36 of the Complaint and, therefore, denies the same.

37. Under the terms of the acquisition, Rebiotix was responsible for the IND and remains responsible for the BLA through FDA approval. After approval, ownership of the BLA will be transferred to Ferring, who will be responsible for marketing and selling RBX2660 and Rebiotix will become the manufacturer of the approved product.

ANSWER: Finch is without sufficient information to form a belief as to the truth of the allegations set forth in Paragraph 37 of the Complaint and, therefore, denies the same.

REBIOTIX'S BLA NO. 125739

38. On May 3, 2021, Rebiotix initiated the rolling submission process for Biologics License Application ("BLA") No. 125739 ("the BLA") seeking regulatory approval to market and sell RBX2660, packaged as a single dose product in a 250 mL ethylene vinyl acetate bag with a single indication: "to reduce the recurrence of *Clostridium difficile* infection (CDI) in adults following antibiotic treatment for recurrent *Clostridium difficile* infection." The BLA rolling submission was completed on November 30, 2021. As allowed by the fast track and breakthrough therapy designations, Rebiotix requested that the BLA receive accelerated approval and priority review.

ANSWER: Finch admits upon information and belief, based on the facts alleged in the Complaint, that Plaintiffs are seeking regulatory approval to market and sell RBX2660, packaged as a single dose product in a 250 mL ethylene vinyl acetate bag with a single indication: "to reduce the recurrence of Clostridium difficile infection (CDI) in adults following antibiotic treatment for recurrent Clostridium difficile infection." Finch admits upon information and belief, based on the facts alleged in the Complaint, that Plaintiffs have completed BLA submission and requested accelerated approval and priority review. Finch is without sufficient information to form a belief as to the truth of the remaining allegations set forth in Paragraph 38 of the Complaint and, therefore, denies the same.

39. Upon receiving FDA approval, Ferring intends to launch a commercial version of RBX2660, which will be manufactured by Rebiotix. Plaintiffs expect that RBX2660 will become the first-ever FDA-approved FMT drug for the treatment of rCDI.

ANSWER: Finch admits upon information and belief, based on the facts alleged in the Complaint, that Plaintiffs intend to launch a commercial version of RBX2660, which will be manufactured by Rebiotix Inc. Finch is without sufficient information to form a belief as to the truth of the remaining allegations set forth in Paragraph 39 of the Complaint and, therefore, denies the same.

40. In addition to the substantial investment in development, clinical trials, and regulatory filings, Ferring has invested substantial resources and effort in understanding the significant unmet medical need for a treatment like RBX2660.

ANSWER: Finch is without sufficient information to form a belief as to the truth of the allegations set forth in Paragraph 40 of the Complaint and, therefore, denies the same.

41. For example, Ferring has already invested significant time and resources engaging with advisory boards and key opinion leaders to understand the clinical need for treatment, the current marketing and development landscape, and areas of unmet need. Ferring has also conducted surveys of healthcare providers, talked with national and regional integrated delivery network providers (i.e., integrated healthcare systems), and spent considerable time and effort understanding the market as a whole and how RBX2660 would be positioned in that market.

ANSWER: Finch is without sufficient information to form a belief as to the truth of the allegations set forth in Paragraph 41 of the Complaint and, therefore, denies the same.

42. Ferring and Rebiotix have also presented the results of their clinical trials through publications, press releases, and at relevant industry conferences including, for example, Digestive Disease Week and the American College of Gastroenterology annual scientific meeting.

ANSWER: Finch is without sufficient information to form a belief as to the truth of the allegations set forth in Paragraph 42 of the Complaint and, therefore, denies the same.

43. Ferring has also been actively engaged in hiring key management and support personnel, developing education materials, and has dedicated numerous employees to approval and launch activities related to RBX2660.

ANSWER: Finch is without sufficient information to form a belief as to the truth of the allegations set forth in Paragraph 43 of the Complaint and, therefore, denies the same.

44. Plaintiffs have made and will continue to make these significant investments in preparation for obtaining expected FDA approval.

ANSWER: Finch is without sufficient information to form a belief as to the truth of the allegations set forth in Paragraph 44 of the Complaint and, therefore, denies the same.

DEFENDANTS' ACTIONS SHOW THERE IS A SUBSTANTIAL CASE OR CONTROVERSY

45. As detailed below, Defendants' actions show that there is a substantial case or controversy between the parties and that such case or controversy is real and immediate, such that resolution now is proper.

ANSWER: Finch states that the allegations set forth in Paragraph 45 and in the heading that immediately precedes Paragraph 45 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Finch states as follows. Except as set forth in Finch's Counterclaims, these allegations are denied.

FTG's S-1 filing

46. On February 26, 2021, FTG submitted an S-1 ("the S-1 filing") with the Securities and Exchange Commission in advance of an anticipated Initial Public Offering. (Ex. 1.) As pled above, on information and belief, defendants FTI and FTH are wholly-owned subsidiaries of FTG.

ANSWER: Finch admits Exhibit 1 appears to be a copy of the Form S-1 Registration Statement it filed with the Securities and Exchange Commission on February 26, 2021. Finch admits that Finch Therapeutics, Inc. and Finch Therapeutics Holdings LLC are wholly-owned subsidiaries of Finch Therapeutics Group, Inc. Finch denies any remaining allegations set forth in Paragraph 46 of the Complaint.

47. The S-1 filing states that the microbiome therapeutic market is "characterized by rapidly changing technologies, significant competition and a strong emphasis on intellectual property." (*Id.* at 134.) The S-1 acknowledges the presence of competitors, specifically naming Plaintiff Rebiotix, and notes that "[a]ny advances in microbiome therapies made by a competitor may be used to develop therapies that could compete against our product candidates." (*Id.*)

ANSWER: Finch admits that the quoted language in Paragraph 47 of the Complaint appears in Exhibit 1 to the Complaint, with the exception of the following correction: ". . . against *any of* our

product candidates" (emphasis added). Finch denies any remaining allegations in Paragraph 47 of the Complaint.

48. In addition, the S-1 acknowledges the highly competitive marketplace stating:

> Our commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Competitors also may obtain FDA, EMA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors.

(*Id.*)

ANSWER: Finch admits that the quoted language in Paragraph 48 of the Complaint appears in Exhibit 1 to the Complaint. Finch denies any remaining allegations in Paragraph 48 of the Complaint.

49. The S-1 filing further explains that competitive products, such as RBX2660, represent a severe threat should they reach the market first, stating:

> Competing products may gain faster or greater market acceptance than our products, if any, and medical advances or rapid technological development by competitors may result in our product candidates becoming non-competitive or obsolete before we are able to recover our research and development and commercialization expenses. If we or our product candidates do not compete effectively, it may have a material adverse effect on our business, financial condition and results of operations.

(*Id.* at 41.)

ANSWER: Finch admits that the quoted language in Paragraph 49 of the Complaint appears in Exhibit 1 to the Complaint. Finch denies any remaining allegations in Paragraph 49 of the Complaint.

50. The S-1 filing states that one of the key advantages of Defendants' platform is the scope and breadth of its patent portfolio. For example, the S-1 filing lists the following as one of the "Key Advantages of Our Platform":

> ***We have built multi-layered patent protection with significant longevity***. We have a large and diverse patent portfolio that embodies pioneering work in the microbiome field. Out patent portfolio consists of over 50 issued U.S. and foreign patents, as well as over 130 patent applications, that have broad relevance for the industry and provide multi-layered protection for our product candidates . . .

(*Id.* at 4 (emphasis in original).)

ANSWER: Finch admits that the quoted language in Paragraph 50 of the Complaint appears in Exhibit 1 to the Complaint. Finch denies any remaining allegations in Paragraph 50 of the Complaint.

51. The S-1 filing indicates that Defendants will actively enforce their patent rights to avoid competition. In addition to the above, the S-1 filing also indicates that the management of Defendants' patent portfolio "leverages both offensive and defensive strategies to protect [their] business," and identifies various tools in their arsenal, including the very patent family at issue here, specifically naming the '107 patent, the '406 patent, and the '413 patent. (*Id.* at 135.) Later, the S-1 filing concludes that "commercial success depends in part on our ability to obtain and maintain proprietary protection," and accordingly, Defendants intend to seek "to prevent others from infringing [their] property rights." (*Id.*)

ANSWER: Finch admits that the quoted language in Paragraph 51 of the Complaint appears in Exhibit 1 to the Complaint, with the exception of the following correction: ". . . *proprietary* rights" (emphasis added). Finch denies any remaining allegations in Paragraph 51 of the Complaint.

52. Thus, Defendants have put investors and the world on notice that (1) they have patents directed to FMT products (including the patents in suit), and (2) they intend to enforce them aggressively against competitors, including Plaintiff Rebiotix.

ANSWER: Finch states that its S-1 filing discloses that Finch has "large and diverse patent portfolio that embodies pioneering work in the microbiome field. Our patent portfolio consists of over 50 issued U.S. and foreign patents, as well as over 130 patent applications, that have broad

relevance for the industry and provide multi-layered protection for our product candidates. . .” Finch denies the remaining allegations set forth in Paragraph 52 of the Complaint as phrased.

Defendants’ patents cover substantially all FMT products, including those products which Defendants are not developing

53. Defendants have attempted to secure broad patent protection for the entire field of FMT, encompassing virtually all FMT technology, including RBX2660. For example, claim 1 of the ’406 patent broadly claims “A pharmaceutical composition comprising an added cryoprotectant and extracted stool bacterial material without fiber.” (Ex. 6 at cl. 1.)

ANSWER: Finch is an industry-leading clinical-stage microbiome therapeutics company developing microbiome therapeutics as potential treatments for gastrointestinal diseases and conditions that extend beyond the gut, including candidates for recurrent *C. difficile*, inflammatory bowel disease, autism spectrum disorder, and chronic hepatitis B. Finch has developed its own technology and has also acquired technology from key innovators in the field, including Dr. Borody and researchers at the University of Minnesota. Finch has invested millions in research and development of microbiome therapeutic treatments, and as a result of its efforts and many innovations, Finch holds a large and diverse patent portfolio of over 200 issued patents and patent applications. Finch admits that claim 1 of the ’406 patent recites “[a] pharmaceutical composition comprising an added cryoprotectant and extracted stool bacterial material without fiber.” Finch states that the remaining allegations set forth in Paragraph 53 of the Complaint and the heading that immediately precedes Paragraph 53 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Finch denies the same.

54. The S-1 filing indicates that Defendants’ lead candidate for a commercial product, CP101, consists of a “lyophilized, intact microbial community harvested from rigorously screened healthy donors and formulated in orally administered capsules designed to release at the appropriate location in the gastrointestinal tract.” (Ex. 1 at 1.) On information and belief, Defendants have not pursued product formulations other than those for oral administration. On information and belief, Defendants have no intention of developing an enema product.

ANSWER: Finch is a clinical-stage microbiome therapeutics company that expands scientific boundaries to deliver novel classes of biological drugs. Finch admits that Exhibit 1 to the Complaint states that "[o]ur lead candidate, CP101, consists of a lyophilized, intact microbial community harvested from rigorously screened healthy donors and formulated in orally administered capsules designed to release at the appropriate location in the gastrointestinal tract." D.I. 1, Ex. 1 at 1. Finch admits that its current product candidates are formulated for oral administration. Finch holds patents directed specifically to "enema products" and "enema delivery systems" and previously manufactured products for OpenBiome for colonoscopy, sigmoidoscopy, or enema delivery. Finch denies the remaining allegations set forth in Paragraph 54 of the Complaint.

55. However, Defendants have sought patent protection for claims directed generally to FMT enema products. For example, on information and belief, FTH is the owner by assignment of the '702 and '309 patents, which issued on November 5, 2019 and June 9, 2020, respectively. These patents generally contain claims directed to enema FMT products, such as Plaintiffs' RBX2660.

ANSWER: Finch admits that the '702 patent issued on November 5, 2019 and is assigned to Finch Therapeutics Holdings LLC. Finch admits that the '309 patent issued on June 9, 2020 and is assigned to Finch Therapeutics Holdings LLC. Finch admits that the '702 and '309 patents include claims directed to an "enema product" or "enema delivery system." Finch denies any remaining allegations set forth in Paragraph 55 of the Complaint.

56. On information and belief, Defendants sought patents such as the '702 patent and '309 patents based on their knowledge of the RBX2660 clinical trial program and the use of RBX2660 under the FDA's enforcement discretion policy. Both the RBX2660 clinical trial program and RBX2660's use under the FDA's enforcement discretion policy were initiated several years before the applications that would mature into the '702 and '309 patents were filed. (*See* Exs. 3, 4.) On information and belief, Defendants filed these applications as part of their offensive strategy to block Plaintiffs from launching their competitive enema product.

ANSWER: Finch admits that the '702 patent issued from Application No. 16/433,437, which was filed June 6, 2019. Finch admits that the '309 patent issued from Application No. 16/703,458,

which was filed December 4, 2019. To the extent the allegations in Paragraph 56 seek privileged information, Finch does not waive the privilege and no response is necessary. Finch denies any remaining allegations set forth in Paragraph 56 of the Complaint.

Defendants have challenged Rebiotix's patent in Europe

57. Rebiotix has prosecuted patents to protect its technology world-wide. On November 24, 2017, the European Patent Office ("EPO") issued an Intention to Grant Notice for one such patent, European Patent Number 3,003,330 ("EP 330"). A true and correct copy of the Intention to Grant Notice is attached as Exhibit 25 and a true and correct copy of EP 330 is attached as Exhibit 26.

ANSWER: Finch admits that page 1 of Exhibit 25 appears to be a communication from the European Patent Office, dated November 24, 2017, which states "[y]ou are informed that the examining division intends to grant a European patent on the basis of the above application, with the text and drawings and the related bibliographic data as indicated below." D.I. 1, Ex. 25 at 1. Finch denies any remaining allegations set forth in Paragraph 57 of the Complaint and the heading that immediately precedes Paragraph 57 of the Complaint.

58. Claim 1 of EP 330 claims:

> A method for manufacturing a microbiota restoration therapy composition, the method comprising:
> collecting a human fecal sample;
> adding a diluent to the human fecal sample to form a diluted sample;
> wherein the diluent includes polyethylene glycol at a concentration of 30-90 g/L;
> mixing the diluted sample with a mixing apparatus;
> filtering the diluted sample;
> wherein filtering forms a filtrate;
> transferring the filtrate to a sample bag; and
> sealing the sample bag.

(Ex. 26 at cl. 1.)

ANSWER: Finch admits that Exhibit 26 appears to be EP 3,003,330 and includes the following claim 1:

> 1. A method for manufacturing a microbiota restoration therapy composition, the method comprising:
>
> collecting a human fecal sample;
>
> adding a diluent to the human fecal sample to form a diluted sample;
>
> wherein the diluent includes polyethylene glycol at a concentration of 30-90 g/L;
>
> mixing the diluted sample with a mixing apparatus;
>
> filtering the diluted sample;
>
> wherein filtering forms a filtrate;
>
> transferring the filtrate to a sample bag; and
>
> sealing the sample bag.

Finch denies any remaining allegations set forth in Paragraph 58 of the Complaint.

59. On February 8, 2019, European Patent Attorneys at TL Brand & Co., 50 Eastcastle Street, London W1W 8EA, Great Britain, filed an opposition to EP 330 "[i]n the name and on behalf of Strawman Limited of Orchard Lea, Horns Lane, Combe, Witney, Oxfordshire, OX29 8NH." (Ex. 27 at 1.) A true and correct copy of the Opposition is attached as Exhibit 27.

ANSWER: Finch admits that Exhibit 27 appears to be an opposition to EP 3,003,330 addressed to the European Patent Office, dated February 8, 2019, and filed by TL Brand & Co. "[i]n the name and on behalf of Strawman Limited of Orchard Lea, Horns Lane, Combe, Witney, Oxfordshire, OX29 8NH, United Kingdom." D.I. 1, Ex. 27 at 1. Finch denies any remaining allegations set forth in Paragraph 59 of the Complaint.

60. According to its website, Strawman Limited indicates that it was created "[t]o relieve you of the time and work in finding a name to front the opposition on behalf of your client." (Ex. 28 at 1.) The "process" section of Strawman Limited's website further states:

> If you wish to oppose a patent and hide behind the name of Strawman Limited ["Strawman™"] the process is very simple.
>
> The European Patent Attorney (or any other legal representative entitled to act before the European Patent Office) fills out the online Application Form. The EPA (or any other legal representative entitled to act before the European Patent Office) may be your own

> selected EPA or may be an EPA selected by another person or organization that acts for you, such as one of your external legal representatives.
>
> That's all there is to it!
>
> There is no requirement to disclose your name and we do not even what to know if you have good cause to file an opposition.

(Ex. 29 at 1.)

ANSWER: Finch admits that Exhibit 28 appears to be a copy of the webpage https://www.strawman.info/about-us.php and contains the language quoted in Paragraph 60 of the Complaint. Exhibit 29 appears to be a copy of the webpage https://www.strawman.info/process---costs.php and contains the language quoted in Paragraph 60 of the Complaint, with the exception of the following correction: ". . . *want* to know. . ." (emphasis added). Finch lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 60 of the Complaint and, therefore, denies the same.

61. TL Brand & Co. is also counsel of record at the EPO for at least certain of the European patents that are related to the patents in suit. Both the patents in suit and their European counterparts are owned by one or more of Defendants. For example, TL Brand & Co., 50 Eastcastle Street, London W1W 8EA (GB) is listed as the representative for European Patent Number 3,701,958, which claims priority to the same Australian patent application and the same four United States Provisional Patent Applications (i.e., United States Provisional Application Number 61/494,363, filed on June 7, 2011, United States Provisional Application Number 61/483,487, filed on May 6, 2011, United States Provisional Application Number 61/451,087, filed on March 9, 2011, and United States Provisional Application Number 61/450,099, filed on March 7, 2011) as the patents in suit. (Ex. 30 at 1.)

ANSWER: Finch admits that Exhibit 30 appears to be a copy of EP 3,701,958 and lists "TL Brand & Co 50 Eastcastle Street London W1W 8EA (GB)" as the representative. Finch admits that EP 3,701,958 lists Thomas Julius Borody as the Applicant and Inventor and that EP 3,701,958 claims priority to United States Provisional Application Number 61/494,363, filed on June 7, 2011, United States Provisional Application Number 61/483,487, filed on May 6, 2011, United States Provisional Application Number 61/451,087, filed on March 9, 2011, United States Provisional

Application Number 61/450,099, filed on March 7, 2011, and Australian Provisional Application AU2010903474, filed on August 4, 2010. Finch states that the remaining allegations set forth in Paragraph 61 of the Complaint are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, Finch denies the same.

62. On information and belief, Defendants or someone acting on behalf of Defendants requested that TL Brand & Co. file an opposition to the EP 330 patent owned by Plaintiff Rebiotix. On information and belief, Defendants or someone acting on behalf of Defendants instructed TL Brand & Co to engage a cover organization (here, Strawman Limited) to serve as the named opponent in the opposition to EP 330 to hide their involvement in the opposition.

ANSWER: Denied.

63. On information and belief, Defendants, either singly or jointly, control, direct, and are responsible for the opposition to EP 330.

ANSWER: Denied.

64. Under the totality of facts and circumstances, there is a definite and concrete controversy between Plaintiffs and Defendants of sufficient immediacy and reality to warrant the issuance of declaratory judgment relief. Plaintiffs seek a judicial determination that the patents in suit are invalid or not infringed.

ANSWER: Finch states that the allegations set forth in Paragraph 64 of the Complaint are conclusions of law as to which no responsive pleading is necessary, but that to the extent any response is required, Finch states as follows. Except as set forth in Finch's Counterclaims, these allegations are denied.

THE PATENTS IN SUIT

65. Each of the patents in suit claims foreign application filing priority to Australian Patent Application Number 2010/903,474, filed on August 4, 2010. In addition, each of the patents in suit claim filing priority to United States Provisional Application Number 61/494,363, filed on June 7, 2011, United States Provisional Application Number 61/483,487, filed on May 6, 2011, United States Provisional Application Number 61/451,087, filed on March 9, 2011, and United States Provisional Application Number 61/450,099, filed on March 7, 2011.

ANSWER: Admitted.

66. The '226 patent was the first in time non-provisional application to be filed in the United States. It was assigned United States Patent Application Number 13/813,915, filed as

PCT/AU2011/000987 on August 4, 2011. Each of the other patents in suit issued from a continuation application that can be traced back to this original filing.

ANSWER: Admitted.

67. On information and belief, the patents in suit each have the same alleged inventor.

ANSWER: Finch admits that the inventor of each of the Patents-in-Suit is Dr. Thomas Borody. Finch denies any remaining allegations set forth in Paragraph 67 of the Complaint.

The '309 Patent

68. On June 9, 2020, the United States Patent and Trademark Office ("PTO") issued the '309 patent, which bears the title "Compositions for fecal floral transplantation and methods for making and using them and devices for delivering them," and names Thomas Borody of Five Dock, Australia as the inventor. A true and correct copy of the '309 patent is attached as Exhibit 2.

ANSWER: Finch admits that on June 9, 2020, the United States Patent and Trademark Office ("PTO") issued the '309 patent, which bears the title "Compositions for fecal floral transplantation and methods for making and using them and devices for delivering them," and names Thomas Borody of Five Dock, Australia as the inventor. Finch denies any remaining allegations set forth in Paragraph 68 of the Complaint.

69. On information and belief, the '309 patent was originally assigned to Crestovo LLC, then Crestovo Holdings LLC, and finally FTH. On information and belief, FTH is now the owner of the '309 patent by assignment recorded at the PTO on December 31, 2020. (Ex. 31.)

ANSWER: Admitted.

The '702 Patent

70. On November 5, 2019, the PTO issued the '702 patent, which bears the title "Compositions for fecal floral transplantation and methods for making and using them and devices for delivering them" and names Thomas J. Borody of Five Dock, Australia as the inventor. A true and correct copy of the '702 patent is attached as Exhibit 3.

ANSWER: Finch admits that on November 5, 2019, the PTO issued the '702 patent, which bears the title "Compositions for fecal floral transplantation and methods for making and using them and

devices for delivering them" and names Thomas J. Borody of Five Dock, Australia as the inventor. Finch denies any remaining allegations set forth in Paragraph 70 of the Complaint.

71. On information and belief, the '702 patent was originally assigned to Crestovo LLC, then Crestovo Holdings LLC, and finally FTH. On information and belief, FTH is now the owner of the '702 patent by assignment recorded at the PTO on December 31, 2020. (Ex. 31.)

ANSWER: Admitted.

The '107 Patent

72. On June 25, 2019, the PTO issued the '107 patent, which bears the title "Compositions for fecal floral transplantation and methods for making and using them and devices for delivering them," and names Thomas Julius Borody of Five Dock, Australia as the inventor. A true and correct copy of the '107 patent is attached as Exhibit 4.

ANSWER: Finch admits that on June 25, 2019, the PTO issued the '107 patent, which bears the title "Compositions for fecal floral transplantation and methods for making and using them and devices for delivering them," and names Thomas Julius Borody of Five Dock, Australia as the inventor. Finch denies any remaining allegations set forth in Paragraph 72 of the Complaint.

73. On information and belief, the '107 patent was originally assigned to Crestovo LLC, then Crestovo Holdings LLC, and finally FTH. On information and belief, FTH is now the owner of the '107 patent by assignment recorded at the PTO on December 31, 2020. (Ex. 31.)

ANSWER: Finch admits that the '107 patent was assigned to Crestovo LLC, then Crestovo Holdings LLC, then Crestovo Investor LLC, then Crestovo Holdings LLC, and finally Finch Therapeutics Holdings LLC. Finch Therapeutics Holdings LLC is the current assignee of the '107 patent by assignment recorded at the PTO on December 31, 2020. Finch denies any remaining allegations set forth in Paragraph 73 of the Complaint.

The '899 patent

74. On September 4, 2018, the PTO issued the '899 patent, which bears the title "Compositions for fecal floral transplantation and methods for making and using them and devices for delivering them" and names Thomas Julius Borody of Five Dock, Australia as the inventor. A true and correct copy of the '899 patent is attached as Exhibit 5.

ANSWER: Finch admits that on September 4, 2018, the PTO issued the '899 patent, which bears the title "Compositions for fecal floral transplantation and methods for making and using them and devices for delivering them" and names Thomas Julius Borody of Five Dock, Australia as the inventor. Finch denies any remaining allegations set forth in Paragraph 74 of the Complaint.

75. On information and belief, the '899 patent was originally assigned to Crestovo LLC, then Crestovo Holdings LLC, and finally FTH. On information and belief, FTH is now the owner of the '899 patent by assignment recorded at the PTO on December 31, 2020. (Ex. 31.)

ANSWER: Finch admits that the '899 patent was assigned to Crestovo LLC, then Crestovo Holdings LLC, then Crestovo Investor LLC, then Crestovo Holdings LLC, and finally Finch Therapeutics Holdings LLC. Finch Therapeutics Holdings LLC is the current assignee of the '899 patent by assignment recorded at the PTO on December 31, 2020. Finch denies any remaining allegations set forth in Paragraph 75 of the Complaint.

The '406 Patent

76. On July 17, 2018, the PTO issued the '406 patent, which bears the title "Compositions for fecal floral transplantation and methods for making and using them and devices for delivering them" and names Thomas Julius Borody of Castle Hill, Australia as the inventor. A true and correct copy of the '406 patent is attached as Exhibit 6.

ANSWER: Finch admits that on July 17, 2018, the PTO issued the '406 patent, which bears the title "Compositions for fecal floral transplantation and methods for making and using them and devices for delivering them" and names Thomas Julius Borody of Castle Hill, Australia as the inventor. Finch denies any remaining allegations set forth in Paragraph 76 of the Complaint.

77. On information and belief, the '406 patent was originally assigned to Crestovo LLC, then Crestovo Holdings LLC, and finally FTH. On information and belief, FTH is now the owner of the '406 patent by assignment recorded at the PTO on December 31, 2020. (Ex. 31.)

ANSWER: Finch admits that the '406 patent was assigned to Crestovo LLC, then Crestovo Holdings LLC, then Crestovo Investor LLC, then Crestovo Holdings LLC, and finally Finch Therapeutics Holdings LLC. Finch Therapeutics Holdings LLC is the current assignee of the '406

patent by assignment recorded at the PTO on December 31, 2020. Finch denies any remaining allegations set forth in Paragraph 77 of the Complaint.

The '413 Patent

78. On May 8, 2018, the PTO issued the '413 patent, which bears the title "Compositions for fecal floral transplantation and methods for making and using them and devices for delivering them" and names Thomas Julius Borody of Five Dock, Australia as the inventor. A true and correct copy of the '413 patent is attached as Exhibit 7.

ANSWER: Finch admits that on May 8, 2018, the PTO issued the '413 patent, which bears the title "Compositions for fecal floral transplantation and methods for making and using them and devices for delivering them" and names Thomas Julius Borody of Five Dock, Australia as the inventor. Finch denies any remaining allegations set forth in Paragraph 78 of the Complaint.

79. On information and belief, the '413 patent was originally assigned to Crestovo LLC, then Crestovo Holdings LLC, and finally FTH. On information and belief, FTH is now the owner of the '413 patent by assignment recorded at the PTO on December 31, 2020. (Ex. 31.)

ANSWER: Finch admits that the '413 patent was assigned to Crestovo LLC, then Crestovo Holdings LLC, then Crestovo Investor LLC, then Crestovo Holdings LLC, and finally Finch Therapeutics Holdings LLC. Finch Therapeutics Holdings LLC is the current assignee of the '413 patent by assignment recorded at the PTO on December 31, 2020. Finch denies any remaining allegations set forth in Paragraph 79 of the Complaint.

The '226 Patent

80. On April 12, 2016, the PTO issued the '226 patent, which bears the title "Compositions for fecal floral transplantation and methods for making and using them and devices for delivering them" and names Thomas Julius Borody of Five Dock, Australia as the inventor. A true and correct copy of the '226 patent is attached as Exhibit 8.

ANSWER: Finch admits that on April 12, 2016, the PTO issued the '226 patent, which bears the title "Compositions for fecal floral transplantation and methods for making and using them and devices for delivering them" and names Thomas Julius Borody of Five Dock, Australia as the inventor. Finch denies any remaining allegations set forth in Paragraph 80 of the Complaint.

81. On information and belief, the ’226 patent was originally assigned to Crestovo LLC, then Crestovo Holdings LLC, and finally FTH. On information and belief, FTH is now the owner of the ’226 patent by assignment recorded at the PTO on December 31, 2020. (Ex. 31.)

ANSWER: Finch admits that the ’226 patent was assigned to Crestovo LLC, then Crestovo Holdings LLC, then Crestovo Investor LLC, then Crestovo Holdings LLC, and finally Finch Therapeutics Holdings LLC. Finch Therapeutics Holdings LLC is the current assignee of the ’226 patent by assignment recorded at the PTO on December 31, 2020. Finch denies any remaining allegations set forth set forth in Paragraph 81 of the Complaint.

COUNT I

Declaratory Judgment of Invalidity of the ’309 Patent

82. Plaintiffs incorporate by reference and repeat the allegations set forth in the preceding paragraphs.

ANSWER: Finch incorporates by reference its responses to Paragraphs 1–81 of the Complaint as if fully set forth herein.

83. An actual, justiciable, and continuing controversy exists between Plaintiffs and Defendants regarding the validity of the ’309 patent.

ANSWER: Finch states that the allegations set forth in Paragraph 83 of the Complaint are conclusions of law as to which no responsive pleading is necessary, but that to the extent any response is required, Finch states as follows. As set forth in Finch’s Counterclaims, an actual controversy exists between Finch and Plaintiffs as to the infringement and validity of the ’309 patent with respect to RBX2660. Finch denies the remaining allegations set forth in Paragraph 83 of the Complaint.

84. Upon obtaining FDA approval, Plaintiffs intend to market RBX2660 in the United States. Due to Defendants’ stated intentions to aggressively enforce their patent portfolio, Plaintiffs reasonably expect that Defendants will assert that the making, using, selling, offering for sale of RBX2660 in the United States, or importation of RBX2660 into the United States infringes the ’309 patent.

ANSWER: Finch admits that making, using, selling, offering for sale of RBX2660 in the United States, or importation of RBX2660 into the United States infringes the '309 patent. Finch denies the remaining allegations set forth in Paragraph 84 of the Complaint.

85. The '309 patent has two independent claims. By way of example, independent claim 1 of the '309 patent claims:

> 1. An enema delivery system configured for transporting to a remote facility, the enema delivery system comprising a container, flexible tubing, and a pharmaceutical composition within the container, wherein the pharmaceutical composition is formulated for enema delivery from the container via the flexible tubing, wherein the pharmaceutical composition comprises saline, a cryoprotectant and a preparation of viable uncultured non-pathogenic fecal bacteria, wherein the fecal bacteria are from a stool of a human donor, wherein the container is sealed, wherein the pharmaceutical composition is free of rough particulate matter, and wherein the pharmaceutical composition is in an amount effective for treating recurrence of *C. difficile* infection.

(Ex. 2 at cl. 1.)

ANSWER: Finch admits that the '309 patent contains two independent claims. Finch admits that claim 1 of the '309 patent recites:

> An enema delivery system configured for transporting to a remote facility, the enema delivery system comprising a container, flexible tubing, and a pharmaceutical composition within the container, wherein the pharmaceutical composition is formulated for enema delivery from the container via the flexible tubing, wherein the pharmaceutical composition comprises saline, a cryoprotectant and a preparation of viable uncultured non-pathogenic fecal bacteria, wherein the fecal bacteria are from a stool of a human donor, wherein the container is sealed, wherein the pharmaceutical composition is free of rough particulate matter, and wherein the pharmaceutical composition is in an amount effective for treating recurrence of C. difficile infection.

86. The claims of the '309 patent are invalid for failure to comply with one or more of the conditions of patentability under Title 35 of the United States Code and related judicial doctrines, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, and/or obviousness-type double patenting. For example, each of the claims of the '309 patent is anticipated or obvious in light of prior art references including, but not limited to, Lund-Tonnesen, Bakken, and Hlavka, either alone or in combination. (Exs. 18, 19, 20, and 23.)

ANSWER: Denied.

87. In addition, the specification of the '309 patent fails to describe or enable, for example, a composition that is "free of rough particulate matter."

ANSWER: Denied.

88. As a result, there exists a substantial controversy between Plaintiffs and Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity.

ANSWER: Denied.

COUNT II

Declaratory Judgment of Noninfringement of the '309 Patent

89. Plaintiffs incorporate by reference and repeat the allegations set forth in the preceding paragraphs.

ANSWER: Finch incorporates by reference its responses to Paragraphs 1–88 of the Complaint as if fully set forth herein.

90. An actual, justiciable, and continuing controversy exists between Plaintiffs and Defendants regarding the infringement of the '309 patent.

ANSWER: Finch states that the allegations set forth in Paragraph 90 of the Complaint are conclusions of law as to which no responsive pleading is necessary, but that to the extent any response is required, Finch states as follows. As set forth in Finch's Counterclaims, an actual controversy exists between Finch and Plaintiffs as to the infringement and validity of the '309 patent with respect to RBX2660. Finch denies the remaining allegations set forth in Paragraph 90 of the Complaint.

91. Upon obtaining FDA approval, Plaintiffs intend to market RBX2660 in the United States. Due to Defendants' stated intentions to aggressively enforce their patent portfolio, Plaintiffs reasonably expect that Defendants will assert that the making, using, selling, offering for sale of RBX2660 in the United States, or importation of RBX2660 into the United States infringes the '309 patent.

ANSWER: Finch admits that making, using, selling, offering for sale of RBX2660 in the United States, or importation of RBX2660 into the United States infringes or will infringe the '309 patent. Finch denies the remaining allegations set forth in Paragraph 91 of the Complaint.

92. Plaintiffs' manufacture, use, sale, offer for sale, or importation of RBX2660 will not infringe, either directly or indirectly, any valid claim of the '309 patent, either literally or under the doctrine of equivalents. For example, RBX2660 is not "free of rough particulate matter" as required by every claim of the '309 patent because a significant amount of particulate matter remains in the suspension when delivered to a patient.

ANSWER: Denied.

93. Additionally, for at least the reasons described above in Count I, the claims of the '309 patent are invalid. Plaintiffs cannot be held liable for infringement of invalid patent claims.

ANSWER: Denied.

94. Plaintiffs are therefore entitled to a judicial declaration that their making, using, selling, offering to sell, or importing of RBX2660 has not infringed and will not infringe any valid claim of the '309 patent.

ANSWER: Denied.

COUNT III

Declaratory Judgment of Invalidity of the '702 Patent

95. Plaintiffs incorporate by reference and repeat the allegations set forth in the preceding paragraphs.

ANSWER: Finch incorporates by reference its responses to Paragraphs 1–94 of the Complaint as if fully set forth herein.

96. An actual, justiciable, and continuing controversy exists between Plaintiffs and Defendants regarding the validity of the '702 patent.

ANSWER: Finch states that the allegations set forth in Paragraph 96 of the Complaint are conclusions of law as to which no responsive pleading is necessary, but that to the extent any response is required, Finch states as follows. As set forth in Finch's Counterclaims, an actual controversy exists between Finch and Plaintiffs as to the infringement and validity of the '702

patent with respect to RBX2660. Finch denies the remaining allegations set forth in Paragraph 96 of the Complaint.

97. Upon obtaining FDA approval, Plaintiffs intend to market RBX2660 in the United States. Due to Defendants' stated intentions to aggressively enforce their patent portfolio, Plaintiffs reasonably expect that Defendants will assert that the making, using, selling, offering for sale of RBX2660 in the United States, or importation of RBX2660 into the United States infringes the '702 patent.

ANSWER: Finch admits that making, using, selling, offering for sale of RBX2660 in the United States, or importation of RBX2660 into the United States infringes or will infringe the '702 patent. Finch denies the remaining allegations set forth in Paragraph 97 of the Complaint.

98. The '702 patent has two independent claims. By way of example, independent claim 1 of the '702 patent claims:

> 1. An enema product configured for transporting to a remote facility, the enema product comprising a container and a pharmaceutical composition within the container, the pharmaceutical composition formulated for enema delivery directly from the container, wherein the container comprises an oxygen-resistant material, and wherein the pharmaceutical composition comprises saline, a cryoprotectant, and the substantially entire microbiota of a stool sample, wherein the pharmaceutical composition is free of rough particulate matter of the stool sample, wherein the substantially entire microbiota is in an amount effective for treating a *C. difficile* infection.

(Ex. 3 at cl. 1.)

ANSWER: Finch admits that the '702 patent contains two independent claims. Finch admits that claim 1 of the '702 patent recites:

> An enema product configured for transporting to a remote facility, the enema product comprising a container and a pharmaceutical composition within the container, the pharmaceutical composition formulated for enema delivery directly from the container, wherein the container comprises an oxygen-resistant material, and wherein the pharmaceutical composition comprises saline, a cryoprotectant, and the substantially entire microbiota of a stool sample, wherein the pharmaceutical composition is free of rough particulate matter of the stool sample, wherein the substantially entire microbiota is in an amount effective for treating a C. difficile infection.

99. The claims of the '702 patent are invalid for failure to comply with one or more of the conditions of patentability under Title 35 of the United States Code and related judicial doctrines, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, and/or obviousness-type double patenting. For example, each of the claims of the '702 patent is anticipated or obvious in light of prior art references including, but not limited to, Lund-Tonnesen, Bakken, and Hlavka, either alone or in combination. (Exs. 18, 19, 20, and 23.)

ANSWER: Denied.

100. In addition, the specification of the '702 patent fails to define, describe, or enable, for example, a composition that comprises "the substantially entire microbiota of a stool sample," that is "free of rough particulate matter," or is "in an amount effective for treating *C. difficile* infection."

ANSWER: Denied.

101. As a result, there exists a substantial controversy between Plaintiffs and Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity.

ANSWER: Denied.

COUNT IV

Declaratory Judgment of Noninfringement of the '702 Patent

102. Plaintiffs incorporate by reference and repeat the allegations set forth in the preceding paragraphs.

ANSWER: Finch incorporates by reference its responses to Paragraphs 1–101 of the Complaint as if fully set forth herein.

103. An actual, justiciable, and continuing controversy exists between Plaintiffs and Defendants regarding the infringement of the '702 patent.

ANSWER: Finch states that the allegations set forth in Paragraph 103 of the Complaint are conclusions of law as to which no responsive pleading is necessary, but that to the extent any response is required, Finch states as follows. As set forth in Finch's Counterclaims, an actual controversy exists between Finch and Plaintiffs as to the infringement and validity of the '702 patent with respect to RBX2660. Finch denies the remaining allegations set forth in Paragraph 103 of the Complaint.

104. Upon obtaining FDA approval, Plaintiffs intend to market RBX2660 in the United States. Due to Defendants' stated intentions to aggressively enforce their patent portfolio, Plaintiffs reasonably expect that Defendants will assert that the making, using, selling, offering for sale of RBX2660 in the United States, or importation of RBX2660 into the United States infringes the '702 patent.

ANSWER: Finch admits that making, using, selling, offering for sale of RBX2660 in the United States, or importation of RBX2660 into the United States infringes or will infringe the '702 patent. Finch denies the remaining allegations set forth in Paragraph 104 of the Complaint.

105. Plaintiffs' manufacture, use, sale, offer for sale, or importation of RBX2660 will not infringe, either directly or indirectly, any valid claim of the '702 patent, either literally or under the doctrine of equivalents. For example, RBX2660 is not "free of rough particulate matter of the stool sample" as required by every claim of the '702 patent because a significant amount of particulate matter from the stool sample remains in the suspension when delivered to a patient.

ANSWER: Denied.

106. Additionally, for at least the reasons described above in Count III, the claims of the '702 patent are invalid. Plaintiffs cannot be held liable for infringement of invalid patent claims.

ANSWER: Denied.

107. Plaintiffs are therefore entitled to a judicial declaration that their making, using, selling, offering to sell, or importing of RBX2660 has not infringed and will not infringe any valid claim of the '309 patent.

ANSWER: Denied.

COUNT V

Declaratory Judgment of Invalidity of the '107 Patent

108. Plaintiffs incorporate by reference and repeat the allegations set forth in the preceding paragraphs.

ANSWER: Finch incorporates by reference its responses to Paragraphs 1–107 of the Complaint as if fully set forth herein.

109. An actual, justiciable, and continuing controversy exists between Plaintiffs and Defendants regarding the validity of the '107 patent.

ANSWER: Finch states that the allegations set forth in Paragraph 109 of the Complaint are conclusions of law as to which no responsive pleading is necessary, but that to the extent any

response is required, Finch states as follows. As set forth in Finch's Counterclaims, an actual controversy exists between Finch and Plaintiffs as to the infringement and validity of the '107 patent with respect to RBX2660. Finch denies the remaining allegations set forth in Paragraph 109 of the Complaint.

110. Upon obtaining FDA approval, Plaintiffs intend to market RBX2660 in the United States. Due to Defendants' stated intentions to aggressively enforce their patent portfolio, Plaintiffs reasonably expect that Defendants will assert that the making, using, selling, offering for sale of RBX2660 in the United States, or importation of RBX2660 into the United States infringes the '107 patent.

ANSWER: Finch admits that making, using, selling, offering for sale of RBX2660 in the United States, or importation of RBX2660 into the United States infringes or will infringe the '107 patent. Finch denies the remaining allegations set forth in Paragraph 110 of the Complaint.

111. The '107 patent has two independent claims. By way of example, independent claim 1 of the '107 patent states:

> 1. A method comprising: receiving at a central location a non-frozen stool sample from a donor, wherein the stool sample is within a stool collection device; testing the stool sample for pathogens; mixing the stool sample with a cryoprotectant to form a mixture; and homogenizing the mixture to produce a composition comprising viable bacteria from the stool sample.

(Ex. 4 at cl. 1.)

ANSWER: Finch admits that the '107 patent has two independent claims. Finch admits that claim 1 of the '107 patent recites:

> A method comprising:
>
> receiving at a central location a non-frozen stool sample from a donor, wherein the stool sample is within a stool collection device;
>
> testing the stool sample for pathogens;
>
> mixing the stool sample with a cryoprotectant to form a mixture; and
>
> homogenizing the mixture to produce a composition comprising viable bacteria from the stool sample.

112. The claims of the '107 patent are invalid for failure to comply with one or more of the conditions of patentability under Title 35 of the United States Code and related judicial doctrines, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, and/or obviousness-type double patenting. For example, each of the claims of the '107 patent is anticipated or obvious in light of prior art references including, but not limited to, Lund-Tonnesen, Bakken, and Hlavka, either alone or in combination. (Exs. 18, 19, 20, and 23.)

ANSWER: Denied.

113. In addition, the specification of the '107 patent fails to define, describe, or enable, for example, "receiving at a central location a non-frozen stool sample from a donor."

ANSWER: Denied.

114. As a result, there exists a substantial controversy between Plaintiffs and Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity.

ANSWER: Denied.

COUNT VI

Declaratory Judgment of Noninfringement of the '107 Patent

115. Plaintiffs incorporate by reference and repeat the allegations set forth in the preceding paragraphs.

ANSWER: Finch incorporates by reference its responses to Paragraphs 1–114 of the Complaint as if fully set forth herein.

116. An actual, justiciable, and continuing controversy exists between Plaintiffs and Defendants regarding the infringement of the '107 patent.

ANSWER: Finch states that the allegations set forth in Paragraph 116 of the Complaint are conclusions of law as to which no responsive pleading is necessary, but that to the extent any response is required, Finch states as follows. As set forth in Finch's Counterclaims, an actual controversy exists between Finch and Plaintiffs as to the infringement and validity of the '107 patent with respect to RBX2660. Finch denies the remaining allegations set forth in Paragraph 116 of the Complaint.

117. For example, upon obtaining FDA approval, Plaintiffs intend to market RBX2660 in the United States. Due to Defendants' stated intentions to aggressively enforce their patent

portfolio, Plaintiffs reasonably expect that Defendants will assert that the making, using, selling, offering for sale of RBX2660 in the United States, or importation of RBX2660 into the United States infringes the '107 patent.

ANSWER: Finch admits that making, using, selling, offering for sale of RBX2660 in the United States, or importation of RBX2660 into the United States infringes or will infringe the '107 patent. Finch denies the remaining allegations set forth in Paragraph 117 of the Complaint.

118. Plaintiffs' manufacture, use, sale, offer for sale, or importation of RBX2660 will not infringe, either directly or indirectly, any valid claim of the '107 patent, either literally or under the doctrine of equivalents. For example, RBX2660 is not manufactured by "receiving at a central location a non-frozen stool sample from a donor, wherein the stool sample is within a stool collection device" as required by every claim of the '107 patent.

ANSWER: Denied.

119. Additionally, for at least the reasons described above in Count V, the claims of the '107 patent are invalid. Plaintiffs cannot be held liable for infringement of invalid patent claims.

ANSWER: Denied.

120. Plaintiffs are therefore entitled to a judicial declaration that their making, using, selling, offering to sell, or importing of RBX2660 has not infringed and will not infringe any valid claim of the '107 patent.

ANSWER: Denied.

COUNT VII

Declaratory Judgment of Invalidity of the '899 Patent

121. Plaintiffs incorporate by reference and repeat the allegations set forth in the preceding paragraphs.

ANSWER: Finch incorporates by reference its responses to Paragraphs 1–120 of the Complaint as if fully set forth herein.

122. An actual, justiciable, and continuing controversy exists between Plaintiffs and Defendants regarding the validity of the '899 patent.

ANSWER: Finch states that the allegations set forth in Paragraph 122 of the Complaint are conclusions of law as to which no responsive pleading is necessary, but that to the extent any response is required, Finch denies the same.

123. Upon obtaining FDA approval, Plaintiffs intend to market RBX2660 in the United States. Due to Defendants' stated intentions to aggressively enforce their patent portfolio, Plaintiffs reasonably expect that Defendants will assert that the making, using, selling, offering for sale of RBX2660 in the United States, or importation of RBX2660 into the United States infringes the '899 patent.

ANSWER: Finch lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 123 of the Complaint and, therefore, denies the same.

124. The '899 patent has two independent claims. By way of example, independent claim 1 of the '899 patent states:

> 1. A method comprising:
> receiving at a central location a stool sample from a healthy donor;
> placing the stool sample within a stool collection device;
> mixing the stool sample with a liquid to form a mixture, wherein the liquid comprises a buffer;
> homogenizing and filtering the mixture to separate fiber from bacteria and produce a filtrate comprising a substantially entire microbiota of the stool sample; and
> selectively removing bacteria from the filtrate to produce a composition comprising bacterial species of the phylum Firmicutes.

(Ex. 5 at cl. 1.)

ANSWER: Finch admits that the '899 patent has two independent claims. Finch admits that claim 1 of the '899 patent recites:

> A method comprising:
>
> receiving at a central location a stool sample from a healthy donor;
>
> placing the stool sample within a stool collection device;
>
> mixing the stool sample with a liquid to form a mixture, wherein the liquid comprises a buffer;
>
> homogenizing and filtering the mixture to separate fiber from bacteria and produce a filtrate comprising a substantially entire microbiota of the stool sample; and
>
> selectively removing bacteria from the filtrate to produce a composition comprising bacterial species of the phylum Firmicutes.

125. The claims of the '899 patent are invalid for failure to comply with one or more of the conditions of patentability under Title 35 of the United States Code and related judicial

doctrines, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, and/or obviousness-type double patenting. For example, each of the claims of the '899 patent is anticipated or obvious in light of prior art references including, but not limited to, Lund-Tonnesen, Bakken, and Hlavka, either alone or in combination. (Exs. 18, 19, 20, and 23.)

ANSWER: Denied.

126. In addition, the specification of the '899 patent fails to define, describe, or enable, for example, a filtrate that comprises "a substantially entire microbiota of the stool sample."

ANSWER: Denied.

127. As a result, there exists a substantial controversy between Plaintiffs and Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity.

ANSWER: Denied.

COUNT VIII

Declaratory Judgment of Noninfringement of the '899 Patent

128. Plaintiffs incorporate by reference and repeat the allegations set forth in the preceding paragraphs.

ANSWER: Finch incorporates by reference its responses to Paragraphs 1–127 of the Complaint as if fully set forth herein.

129. An actual, justiciable, and continuing controversy exists between Plaintiffs and Defendants regarding the infringement of the '899 patent.

ANSWER: Finch states that the allegations set forth in Paragraph 129 of the Complaint are conclusions of law as to which no responsive pleading is necessary, but that to the extent any response is required, Finch denies the same.

130. Upon obtaining FDA approval, Plaintiffs intend to market RBX2660 in the United States. Due to Defendants' stated intentions to aggressively enforce their patent portfolio, Plaintiffs reasonably expect that Defendants will assert that the making, using, selling, offering for sale of RBX2660 in the United States, or importation of RBX2660 into the United States infringes the '899 patent.

ANSWER: Finch lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 130 of the Complaint and, therefore, denies the same.

131. Plaintiffs' manufacture, use, sale, offer for sale, or importation of RBX2660 will not infringe, either directly or indirectly, any valid claim of the '899 patent, either literally or under the doctrine of equivalents. For example, RBX2660 suspension does not contain a buffer as required by every claim of the '899 patent.

ANSWER: Finch lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 131 of the Complaint and, therefore, denies the same.

132. Additionally, for at least the reasons described above in Count VII, the claims of the '899 patent are invalid. Plaintiffs cannot be held liable for infringement of invalid patent claims.

ANSWER: Denied.

133. Plaintiffs are therefore entitled to a judicial declaration that their making, using, selling, offering to sell, or importing of RBX2660 has not infringed and will not infringe any valid claim of the '899 patent.

ANSWER: Finch lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 133 of the Complaint and, therefore, denies the same.

COUNT IX

Declaratory Judgment of Invalidity of the '406 Patent

134. Plaintiffs incorporate by reference and repeat the allegations set forth in the preceding paragraphs.

ANSWER: Finch incorporates by reference its responses to Paragraphs 1–133 of the Complaint as if fully set forth herein.

135. An actual, justiciable, and continuing controversy exists between Plaintiffs and Defendants regarding the validity of the '406 patent.

ANSWER: Finch states that the allegations set forth in Paragraph 135 of the Complaint are conclusions of law as to which no responsive pleading is necessary, but that to the extent any response is required, Finch denies the same.

136. Upon obtaining FDA approval, Plaintiffs intend to market RBX2660 in the United States. Due to Defendants' stated intentions to aggressively enforce their patent portfolio, Plaintiffs reasonably expect that Defendants will assert that the making, using, selling, offering for sale of

RBX2660 in the United States, or importation of RBX2660 into the United States infringes the '406 patent.

ANSWER: Finch lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 136 of the Complaint and, therefore, denies the same.

137. The '406 patent has two independent claims. By way of example, independent claim 1 of the '406 patent states:

> 1. A pharmaceutical composition comprising an added cryoprotectant and extracted stool bacterial material without fiber.

(Ex. 6 at cl. 1.)

ANSWER: Finch admits that the '406 patent has two independent claims. Finch admits that claim 1 of the '406 patent recites:

> A pharmaceutical composition comprising an added cryoprotectant and extracted stool bacterial material without fiber.

138. The claims of the '406 patent are invalid for failure to comply with one or more of the conditions of patentability under Title 35 of the United States Code and related judicial doctrines, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, and/or obviousness-type double patenting. For example, each of the claims of the '406 patent is anticipated or obvious in light of prior art references including, but not limited to, Lund-Tonnesen, Bakken, and Hlavka, either alone or in combination. (Exs. 18, 19, 20, and 23.)

ANSWER: Denied.

139. In addition, the specification of the '406 patent fails to define, describe, or enable, for example, a composition that comprises "extracted stool bacterial material without fiber."

ANSWER: Denied.

140. As a result, there exists a substantial controversy between Plaintiffs and Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity.

ANSWER: Denied.

COUNT X

Declaratory Judgment of Noninfringement of the '406 Patent

141. Plaintiffs incorporate by reference and repeat the allegations set forth in the preceding paragraphs.

ANSWER: Finch incorporates by reference its responses to Paragraphs 1–140 of the Complaint as if fully set forth herein.

142. An actual, justiciable, and continuing controversy exists between Plaintiffs and Defendants regarding the infringement of the '406 patent.

ANSWER: Finch states that the allegations set forth in Paragraph 142 of the Complaint are conclusions of law as to which no responsive pleading is necessary, but that to the extent any response is required, Finch denies the same.

143. Upon obtaining FDA approval, Plaintiffs intend to market RBX2660 in the United States. Due to Defendants' stated intentions to aggressively enforce their patent portfolio, Plaintiffs reasonably expect that Defendants will assert that the making, using, selling, offering for sale of RBX2660 in the United States, or importation of RBX2660 into the United States infringes the '406 patent.

ANSWER: Finch lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 143 of the Complaint and, therefore, denies the same.

144. Plaintiffs' manufacture, use, sale, offer for sale, or importation of RBX2660 will not infringe, either directly or indirectly, any valid claim of the '406 patent, either literally or under the doctrine of equivalents. For example, the RBX 2660 suspension does not contain (i) "extracted stool bacterial material without fiber" and is not (ii) "free of rough particulate matter" as required by every claim of the '406 patent.

ANSWER: Finch lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 144 of the Complaint and, therefore, denies the same.

145. Additionally, for at least the reasons described above in Count IX, the claims of the '406 patent are invalid. Plaintiffs cannot be held liable for infringement of invalid patent claims.

ANSWER: Denied.

146. Plaintiffs are therefore entitled to a judicial declaration that their making, using, selling, offering to sell, or importing of RBX2660 has not infringed and will not infringe any valid claim of the '406 patent.

ANSWER: Finch lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 146 of the Complaint and, therefore, denies the same.

COUNT XI

Declaratory Judgment of Invalidity of the '413 Patent

147. Plaintiffs incorporate by reference and repeat the allegations set forth in the preceding paragraphs.

ANSWER: Finch incorporates by reference its responses to Paragraphs 1–146 of the Complaint as if fully set forth herein.

148. An actual, justiciable, and continuing controversy exists between Plaintiffs and Defendants regarding the validity of the '413 patent.

ANSWER: Finch states that the allegations set forth in Paragraph 148 of the Complaint are conclusions of law as to which no responsive pleading is necessary, but that to the extent any response is required, Finch denies the same.

149. Upon obtaining FDA approval, Plaintiffs intend to market RBX2660 in the United States. Due to Defendants' stated intentions to aggressively enforce their patent portfolio, Plaintiffs reasonably expect that Defendants will assert that the making, using, selling, offering for sale of RBX2660 in the United States, or importation of RBX2660 into the United States infringes the '413 patent.

ANSWER: Finch lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 149 of the Complaint and, therefore, denies the same.

150. The '413 patent has two independent claims. By way of example, independent claim 1 of the '413 patent states:

> 1. A method comprising: receiving a stool sample from a healthy donor at a central location, wherein the donor has been prescreened for infectious agents; placing the stool sample within a stool collection device; mixing the stool sample with a liquid to form a mixture, wherein the liquid comprises a buffer and a cryoprotectant; homogenizing and filtering the mixture to separate fiber from bacteria and produce a filtrate comprising a substantially entire microbiota of the stool sample.

(Ex. 7 at cl. 1.)

ANSWER: Finch admits that the '413 patent has two independent claims. Finch admits that claim 1 of the '413 patent recites:

> A method comprising:
>
> receiving a stool sample from a healthy donor at a central location, wherein the donor has been prescreened for infectious agents;
>
> placing the stool sample within a stool collection device;
>
> mixing the stool sample with a liquid to form a mixture, wherein the liquid comprises a buffer and a cryoprotectant;
>
> homogenizing and filtering the mixture to separate fiber from bacteria and produce a filtrate comprising a substantially entire microbiota of the stool sample.

151. The claims of the '413 patent are invalid for failure to comply with one or more of the conditions of patentability under Title 35 of the United States Code and related judicial doctrines, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, and/or obviousness-type double patenting. For example, each of the claims of the '413 patent is anticipated or obvious in light of prior art references including, but not limited to, Lund-Tonnesen, Bakken, and Hlavka, either alone or in combination. (Exs. 18, 19, 20, and 23.)

ANSWER: Denied.

152. In addition, the specification of the '413 patent fails to define, describe, or enable, for example, a filtrate that comprises "a substantially entire microbiota of the stool sample."

ANSWER: Denied.

153. As a result, there exists a substantial controversy between Plaintiffs and Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity.

ANSWER: Denied.

COUNT XII

Declaratory Judgment of Noninfringement of the '413 Patent

154. Plaintiffs incorporate by reference and repeat the allegations set forth in the preceding paragraphs.

ANSWER: Finch incorporates by reference its responses to Paragraphs 1–153 of the Complaint as if fully set forth herein.

155. An actual, justiciable, and continuing controversy exists between Plaintiffs and Defendants regarding the infringement of the '413 patent.

ANSWER: Finch states that the allegations set forth in Paragraph 155 of the Complaint are conclusions of law as to which no responsive pleading is necessary, but that to the extent any response is required, Finch denies the same.

156. Upon obtaining FDA approval, Plaintiffs intend to market RBX2660 in the United States. Due to Defendants' stated intentions to aggressively enforce their patent portfolio, Plaintiffs reasonably expect that Defendants will assert that the making, using, selling, offering for sale of RBX2660 in the United States, or importation of RBX2660 into the United States infringes the '413 patent.

ANSWER: Finch lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 156 of the Complaint and, therefore, denies the same.

157. Plaintiffs' manufacture, use, sale, offer for sale, or importation of RBX2660 will not infringe, either directly or indirectly, any valid claim of the '413 patent, either literally or under the doctrine of equivalents. For example, RBX2660 suspension does not contain a buffer as required by every claim of the '413 patent.

ANSWER: Finch lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 157 of the Complaint and, therefore, denies the same.

158. Additionally, for at least the reasons described above in Count XI, the claims of the '413 patent are invalid. Plaintiffs cannot be held liable for infringement of invalid patent claims.

ANSWER: Denied.

159. Plaintiffs are therefore entitled to a judicial declaration that their making, using, selling, offering to sell, or importing of RBX2660 has not infringed and will not infringe any valid claim of the '413 patent.

ANSWER: Finch lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 159 of the Complaint and, therefore, denies the same.

COUNT XIII

Declaratory Judgment of Invalidity of the '226 Patent

160. Plaintiffs incorporate by reference and repeat the allegations set forth in the preceding paragraphs.

ANSWER: Finch incorporates by reference its responses to Paragraphs 1–159 of the Complaint as if fully set forth herein.

161. An actual, justiciable, and continuing controversy exists between Plaintiffs and Defendants regarding the validity of the ’226 patent.

ANSWER: Finch states that the allegations set forth in Paragraph 161 of the Complaint are conclusions of law as to which no responsive pleading is necessary, but that to the extent any response is required, Finch denies the same.

162. Upon obtaining FDA approval, Plaintiffs intend to market RBX2660 in the United States. Due to Defendants’ stated intentions to aggressively enforce their patent portfolio, Plaintiffs reasonably expect that Defendants will assert that the making, using, selling, offering for sale of RBX2660 in the United States, or importation of RBX2660 into the United States infringes the ’226 patent.

ANSWER: Finch lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 162 of the Complaint and, therefore, denies the same.

163. The ’226 patent has three independent claims. By way of example, independent claim 1 of the ’226 patent states:

> 1. An oxygen-free or substantially oxygen-free pharmaceutical preparation, comprising:
> (a) a formulation comprising:
> (i) a frozen, freeze-dried, spray-dried, lyophilized or powdered entire or at least 90% anaerobic microorganism population of a complete microbiota of a fecal sample; or
> (ii) all or at least 90% anaerobic microorganism population of a complete microbiota of a fecal sample in an excipient, a saline, a buffer, a buffering agent or medium, or a fluid-glucose-cellobiose agar (RGCA) medium,
> (b) an oxygen scavenging material, and
> (c) an air tight or an anaerobic container,
> wherein the pharmaceutical preparation provides an at least about 99.5% oxygen-free or oxygen-free containment or storage of the anaerobic microorganism population of (a)(i) or (a)(ii) in the air tight or the anaerobic container.

(Ex. 8 at cl. 1.)

ANSWER: Finch admits that the '226 patent has three independent claims. Finch admits that claim 1 of the '226 patent recites:

> An oxygen-free or substantially oxygen-free pharmaceutical preparation, comprising:
>
> (a) a formulation comprising:
>
> (i) a frozen, freeze-dried, spray-dried, lyophilized or powdered entire or at least 90% anaerobic microorganism population of a complete microbiota of a fecal sample; or
>
> (ii) all or at least 90% anaerobic microorganism population of a complete microbiota of a fecal sample in an excipient, a saline, a buffer, a buffering agent or medium, or a fluid-glucose-cellobiose agar (RGCA) medium,
>
> (b) an oxygen scavenging material, and
>
> (c) an air tight or an anaerobic container,
>
> wherein the pharmaceutical preparation provides an at least about 99.5% oxygen-free or oxygen-free containment or storage of the anaerobic microorganism population of (a)(i) or (a)(ii) in the air tight or the anaerobic container.

164. The claims of the '226 patent are invalid for failure to comply with one or more of the conditions of patentability under Title 35 of the United States Code and related judicial doctrines, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, and/or obviousness-type double patenting. For example, each of the claims of the '226 patent is anticipated or obvious in light of prior art references including, but not limited to, Lund-Tonnesen, Bakken, and Hlavka, either alone or in combination. (Exs. 18, 19, 20, and 23.)

ANSWER: Denied.

165. In addition, the specification of the '226 patent fails to define, describe, or enable, for example, either a composition that comprises "all or at least 90% anaerobic microorganism population of a complete microbiota of a fecal sample" or an "entire or at least 90% anaerobic microorganism population of a complete microbiota of a fecal sample."

ANSWER: Denied.

166. As a result, there exists a substantial controversy between Plaintiffs and Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity.

ANSWER: Denied.

COUNT XIV

Declaratory Judgment of Noninfringement of the ’226 Patent

167. Plaintiffs incorporate by reference and repeat the allegations set forth in the preceding paragraphs.

ANSWER: Finch incorporates by reference its responses to Paragraphs 1–166 of the Complaint as if fully set forth herein.

168. An actual, justiciable, and continuing controversy exists between Plaintiffs and Defendants regarding the infringement of the ’226 patent.

ANSWER: Finch states that the allegations set forth in Paragraph 168 of the Complaint are conclusions of law as to which no responsive pleading is necessary, but that to the extent any response is required, Finch denies the same.

169. Upon obtaining FDA approval, Plaintiffs intend to market RBX2660 in the United States. Due to Defendants’ stated intentions to aggressively enforce their patent portfolio, Plaintiffs reasonably expect that Defendants will assert that the making, using, selling, offering for sale of RBX2660 in the United States, or importation of RBX2660 into the United States infringes the ’226 patent.

ANSWER: Finch lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 169 of the Complaint and, therefore, denies the same.

170. Plaintiffs’ manufacture, use, sale, offer for sale, or importation of RBX2660 will not infringe, either directly or indirectly, any valid claim of the ’226 patent, either literally or under the doctrine of equivalents. For example, RBX2660 suspension does not contain an oxygen scavenging material as required by every claim of the ’226 patent.

ANSWER: Finch lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 170 of the Complaint and, therefore, denies the same.

171. Additionally, for at least the reasons described above in Count XIII, the claims of the ’226 patent are invalid. Plaintiffs cannot be held liable for infringement of invalid patent claims.

ANSWER: Denied.

172. Plaintiffs are therefore entitled to a judicial declaration that their making, using, selling, offering to sell, or importing of RBX2660 has not infringed and will not infringe any valid claim of the '226 patent.

ANSWER: Finch lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 172 of the Complaint and, therefore, denies the same.

PRAYER FOR RELIEF

The remainder of the Complaint is a Prayer for Relief, as to which no response is necessary. To the extent any response is required, Finch denies that Plaintiffs are entitled to any remedy or relief, and denies any allegations therein.

AFFIRMATIVE AND OTHER DEFENSES

Finch hereby asserts the following affirmative defenses without undertaking or otherwise shifting any applicable burdens of proof. Finch reserves the right to assert additional defenses, as warranted by facts learned through investigation and discovery.

FIRST DEFENSE

Plaintiffs have failed to state a claim on which relief can be granted.

SECOND DEFENSE

Plaintiffs infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more valid and enforceable claims of at least the '107, '309, and '702 patents. On information and belief, discovery will reveal information supporting a finding of Plaintiffs' infringement of one or more of the other Patents-in-Suit.

THIRD DEFENSE

All Patents-in-Suit are valid and comply with the conditions of patentability under Title 35 of the United States Code and related judicial doctrines, including but not limited to, 35 U.S.C. §§ 101, 102, 103 and 112 and/or obviousness type double patenting.

FOURTH DEFENSE

Plaintiffs' action is not an "exceptional" case in Plaintiffs' favor, and Plaintiffs therefore may not recover, in whole or in part, its attorneys' fees and any costs under 35 U.S.C. § 285 or any other applicable law.

RESERVATION OF DEFENSES

Finch reserves its right to assert any additional defenses or counterclaims, at law or equity, which may exist.

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